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At the Bedside

Families, Strangers, and Those Most Alone: Insights from Cultures, Including Our Own

Edmund G. Howe

ABSTRACT

In this introduction to this issue of *The Journal of Clinical Ethics* (*JCE*), I will discuss the legacy of our recently departed friend and colleague, Edmund D. Pellegrino, MD. In this light, I will discuss three articles in this issue of the journal that provide insight into the cultures of China, Mexico, and the U.S., and propose alternative approaches for careproviders in the U.S. to include in their practice as they work with patients and family members at the end of life.

A dear friend has left us.

Edmund D. Pellegrino, MD, a most eminent physician and ethicist, recently has died. In the first part of this introduction, I shall say a bit about him, including who he was to me, referring to him as "Ed," as I think he would have liked.

I will then discuss three articles included in this issue of *The Journal of Clinical Ethics* that involve different cultures: China, Mexico, and the U.S. The influence of culture was one of Ed's core concerns.[1]

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First, I will consider the importance of family to elderly Chinese-Americans, and the possibility that patients may not want to know when they have an incurable illness. Second, I will discuss a study that asked men from Mexico whether they would donate an organ to a stranger. Their answers may not reflect their culture, and whether they would actually do as they say may be open to question, but their responses challenge us to reconsider how we should treat strangers. Third, in a case from the U.S., a patient with a history of sexual "predatory" behavior toward children has a brain tumor that is probably operable. In addition to other questions, his plight raises a concern that I see as the most important of all. Namely, how, in the U.S., we treat those who are the most alone.

Finally, I will present the most difficult real case I ever encountered, that involves the influence of culture. It is one I put to Ed before 170 medical students. He preferred that format to giving planned presentations. I will tell what happened and how Ed responded.

DR. PELLEGRINO AND HIS LEGACY

When I was first asked to become editor-in-chief of *JCE* 25 years ago, Ed was the first person I called, to ask if he would be willing to be on our editorial board. He said yes.[2] After that, the other "leaders in ethics" whom I called accepted. They could not have

felt better when accepting than knowing that Ed was already aboard. I first met Ed when he was the president of Catholic University. I was in a group of faculty who sought Ed's insights on a plan to offer fourth-year medical students an ethics elective that combined the resources of our four schools—which we accomplished.[3] I came to know Ed better still as I asked him each year to speak to medical students at the Uniformed Services University of the Health Sciences (USUHS), where I teach.

Ed instructed students, always, on the moral commitment that careproviders make from the moment they first offer to treat a patient. They make this promise, he'd say, when the patient is most vulnerable, and so this promise is not that of a "used-car salesman," and may involve self-sacrifice.

Ed shared, too, his "secret" for interviewing students applying to medical school. He asked them harder and harder questions until they didn't have an answer. If they told Ed "I don't know," they were "probably OK." But if they didn't, it was likely they weren't. Ed emphasized the all-importance of integrity, of doing what is right, even when "no one is looking." This captures who Ed was. It is this trait, his integrity that caused me, when I become stuck, to ask myself, "What *Ed* would do?"

Finally, I should add that Ed, while lecturing, would, without exception, spot a student not paying attention. He would leap up the stairs of the amphitheater, literally, even in his later years, until he reached the row the student was in. He'd wait there until the student noticed the silence and would look up. Each year, before he came to speak to my students, I would inform them he would do this. (I would say I was doing this to add to my "ethics cred.") To emphasize the benefits of providing prior information, I would assure the students, "*He will do this*." Ed never proved me wrong.

LESSONS FROM THREE CULTURES

Of China, and of the Importance of Family

In this issue of *JCE,* Karen C. Chan, in "Challenges to Culturally Sensitive Care for Elderly Patients: A First-Generation Chinese-American Perspective," describes how Chinese cultural beliefs may differ from those in the U.S.[4] She reports, for example, that confidentiality, as found in the West, is "foreign" in the East. She reports that families protect aged patients from hearing "bad news," and Chinese physicians often are willing to *lie* to patients when their family members request this. Chan reports that an ongoing effort, the ENABLE Project (the Empowerment Network for Adjustment to Bereavement and Loss in End-of-life) in Hong Kong, is trying to change this, so that people there can adopt Western moral values. This makes some sense, because autonomy is very important. Yet there may be substantial compensatory gains from more traditional practices such as placing great importance on family. I will explore this, and what we might most learn from them.

The Importance of Family

Chinese parents, when they age, may accept their adult children making medical decisions for them. They may accept this even when they are competent and when their children's decisions differ from their own. Chan explains why: to these patients, there is nothing more important than maintaining good family relationships. The gains that patients may have from this value priority are hardly trivial. In my own psychiatric practice, I experience, as do other therapists, the harms that families can inflict. Adult siblings battle over who will get a dying parent's inheritance, and then they no longer speak to each other. Adult children may end contact with a parent, once they can, because the parent, verbally or even physically, continues to abuse them. (Ending contact may be the best choice they have.) Aged parents may not give adult children any information when they are hospitalized because they are afraid how their children might use this information against them. One aged patient said, for example, "My son might use this information to try to 'put me away'." (It was not a wholly irrational fear). On the other hand, I and other therapists see how families may benefit a patient most profoundly.

An example is how parents can help an adult child who has severe psychiatric illness such as schizophrenia or bipolar illness. When the patient loses touch with reality, it may occur rapidly, and he or she may suddenly get much worse. Family members may discern this well before the patient does, can share this information with the patient, and thus the patient may be able to get the immediate care needed, and perhaps avoid hospitalization. If a patient can avoid repeated hospitalization, it may profoundly change his or her quality of life. Careproviders can also help families gain such skills to help patients do as well as possible. One example is that a patient with schizophrenia—like anyone else—may do much worse when family members are overly critical. Careproviders in China and in the U.S. have taught family members to "stop." In China, the rate of hospitalization of patients with schizophrenia is eight times less than it was.[5]

Family harmony may have protective, "preventative" benefits. There is evidence that children who grow up in close families may become more "resilient" or better able to cope with stress.[6] The extent to which a family can affect its members has few limits. Family arguments may harm infants as they sleep![7] Family members may benefit a patient, particularly at the end of life. A remarkable and even surprising example is that a family may experience, together, a profound sense of meaning and emotional richness even when a parent has Alzheimer's disease and "loses it" increasingly as he or she ages.

I think of a man whose mother has severe dementia. As she got worse, he became increasingly distraught. I told him what I had seen: that some adult children find and report that these days with their parents are the best days of their lives. Why? Because they find, in spite of what they expect, that, during this time, they feel an emotional closeness with their parents they never felt before. They interact, for example, by touching. They miss interacting verbally, but they can share that kind of closeness with other people. This man told me later that my telling him this somehow enabled him—and his mother—to change their lives very significantly. Somehow my telling him this enabled him to cherish what he *had* with his mother, rather than focus on what he and she had lost. He acknowledged, for the first time, that previously, throughout their lives, they had mostly argued. He now relishes each moment they still have together.

In these ways, Chinese patients may find family harmony especially rewarding. They may not have the same kind of personal autonomy we value in the U.S., but the priority they give to family harmony may be a substantial gain. This may be even more true for them because, like most people, their feelings are deeply allied with their cultural beliefs. As Greene says, people "are more committed to their ways of life than they are to producing good results."[8] In light of this, they may place greater value on the needs and wants of their family than on their own needs and wants, especially at the end of life. What, then, may be some clinical implications for careproviders practicing in the U.S.?

Clinical Implications

Patients' choices, when dying, are limited. They may, for instance, be able to choose only between an experimental treatment that enables them to live longer but with more pain, or the standard of care that may result in their not living as long.[9] Under these circumstances, they may want whatever their families would need or want, more than what they need or want. This preference may be conscious or unconscious. Careproviders, here, as those in China, may find ways to follow what families decide. In China, patients may want this to a greater extent because it is part of their culture.

Should We Make It Easier for Patients to Make Decisions in their Family's Interests?

There are essentially three ways that careproviders might further patients' desires to meet the needs and wants of family members to a greater extent than we usually do. These are: (1) careproviders can "promote" this as an option when patients are competent; (2) careproviders can help family surrogate decision makers use this approach when patients are no longer competent; and (3) careproviders may give greater priority to meeting the needs and wants of family members when careproviders serve as ethics consultants.

1. When patients are competent, careproviders can take the initiative to inquire whether patients might want to make decisions based on their family's interests. For example, in earlier issues of *JCE,* Jeffrey T. Berger has written about patients' concerns that they not be a burden to family members: "A main concern of patients is not to burden their family members, and this concern often influences patients' preferences for medical care. Types of burdens that are of concern to patients include emotional burdens, financial burdens, and physical burdens for relatives who directly provide care."[10] Given these concerns, careproviders may ask patients questions they usually might not think to ask. In addition to asking patients what they want, careproviders can ask patients if they want to discuss what they think their family members might want. To soften a possible harmful connotation of this question, careproviders can say, "I ask because some patients want to talk about these kinds of things, and some patients don't." Because, of course, if patients don't want to talk about these things, it could imply that they care more about what they want than about what their family members need and want.

When patients are interested in discussing their family members' needs and wants, it might be helpful for careproviders to provide an example. For instance, careproviders can explain that family members may have their own unique response to the patient's illness: "Some family members can find great meaning in being with their parent at the bedside—being able to touch them. But other family members might find this emotionally excruciating, and avoid it, and they may feel guilty about it."

A possible downside to this approach is that some patients might then think they should consider the feelings of their loved ones when they haven't. On the other hand, some patients may not consider these things before careproviders raise the issues explicitly, and, if careproviders don't, the patients may later regret that this didn't occur to them. Still other patients may struggle with these kinds of concerns on their own, and feeling alone can be the source of exceptional pain.

Being a financial burden on family members is a common concern. Careproviders might ask patients, "Would you want to discuss the concerns your family may have about money?" There may be a downside to beginning this conversation: it may imply patients *should* consider it. But, as above, unless careproviders ask, some patients may not consider it and later wish they had, or, if they do consider it, they may not feel able to discuss it with anyone.

Finally, careproviders can ask a more general question: "If you could no longer make decisions for yourself, would you want your family to make decisions for you based on what they think *you* would want, or that are based on what *they* would want?"

2. Empowering a surrogate decision maker. When patients say what they really want is what family members would want, this can be stated in an advance directive. But even when patients put it in an advance directive, the person who is tasked with implementing the directive may not follow it. The implementer may reason, "The family's task is to say what the *patient* would want, not what *they* would want for themselves!" Given this, careproviders could suggest to patients who feel this way that they should not only put this in an advance directive, but should also tell whomever will make decisions for them that this is what they really want.

Careproviders can also tell the patient's surrogate decision maker how best to bring about what the patient wants, given current U.S. cultural values. Then, should the patient become incompetent, family members can say what *they* want, but present it as what they believe the *patient* would have wanted. Some may ask whether this is ethical, but, on a deeper level, this is what the patient had previously said he or she wanted.

In this way, careproviders can inform patients and families, early on, about how the U.S. system currently "works." That is, ethically—if not legally—families and other surrogate decision makers will be asked to say not what they want, but what the patient would have wanted, and implementers may hesitate when family members say that what the patient would have wanted is what they, the family members, want. Some who question whether this is ethical might also assert that careproviders should instead try to change our present "system." But, for now, the approach I'm describing may be the only way that a patient and family members can both have what they want. Ethically, careproviders who use this approach are telling patients and family members the *truth*, and are alerting patients and family members about this truth early enough that they have time to make some choices—that is, while the patients can express their preferences.

This approach exemplifies a subtle, wider-reaching guideline that is almost always applicable: that careproviders should, in general, tell patients and all of their loved ones all that they know that could be a factor in what patients and families will need to make the decisions that face them.[11] As a practical tool for determining when to do this, careproviders can ask themselves what patients and loved ones would know if they were specialists in the medical area in which the patient is ill, lawyers, and ethicists—all combined!

3. Options for ethics consultants. Careproviders often serve as ethics consultants—formally or informally. When family members must make decisions for an incapacitated patient, one thing an ethics consultant can do is provide the family with legal information on how members of a family are prioritized as decision makers. When it is clear that an incompetent patient's preference was to meet family members' needs and wants, however, rather than provide family with legal materials, ethics consultants may instead encourage family members to discuss, together, what decisions should be made, so that all involved can come to agree on what *they* most want for the patient. I hope that the core justification for this is self-evident: when patients are not able to say what they would have wanted prior to becoming incompetent, such family discussion may be the best and only way with the greatest likelihood of bringing about what, at the deepest level, most patients would most genuinely want.

To repeat: the ethical presupposition underlying this approach is that it is what most patients, if asked, would probably want. Most patients will say that they would want what their family feels is best for *them*. Here is an example how this can, and has, been carried out. The patient was in a coma; he had untreatable cancer, with, at most, six months to live. The coma was caused by an infected abscess in a

nasal sinus that antibiotics weren't reaching. His careproviders thought surgery could drain the abscess sufficiently for the antibiotics to work. But even if surgery did work to the extent that the patient regained consciousness, no one could guess whether he would *want* to regain consciousness, because, regardless, he would die within a few months. His wife said "no" to the surgery, but his children said "yes." State law said the wife was the patient's highest "prioritized" surrogate decision maker, and she should say what she thought he would want. Of course, if her decision trumped, the children's task would be, if possible, to forgive her. But there was another route: the family could choose *together*—which is what they did. Encouraged by the ethics consultants (of which I was one), the family agreed the patient should have the surgery and a DNR (do-not-resuscitate) order. But, to everyone's surprise, before surgery, the antibiotics started to work, and the patient regained consciousness. He was able to say that he *wouldn't* have wanted surgery, and, in a few months, he died, as predicted.[12]

Should We Be Less Concerned than Usual about Being Sure Patients Really Know They Are Going to Die?

Chinese doctors, Chan relates, often don't tell parents they are dying, at their family's request. This raises several questions. For example, how do these patients, their families, and their doctors all fare in this kind of situation? This also raises the clinical question, particularly applicable to us in the U.S., of whether we should, in general, try to insure that patients know they are dying, to the extent that we do. For example, how much information should we give patients, and at what times? A specific context in which this conflict recently has arisen is in response to a legal requirement enacted in the State of New York—and elsewhere—in February 2011: the Palliative Information Act "mandates" that if a patient is diagnosed with terminal illness, the patient's careprovider must offer to give the patient full information regarding the patient's legal rights to palliative care and all other options.[13]

This law mandates what would seem to be optimal care. I recall, for example, how nurses at one hospital once contacted me and asked me to consult with all of the staff working in their specialty service, because the doctors were telling fatally ill patients only about the options of receiving the standard of care or of entering a research protocol. Physicians were not, the nurses said, telling patients about the option of palliative care. (I shall add that these patients had, in general, a fourth option: to ask careproviders to "do nothing." Of course, I would ask a patient if he or she chose this option, "Why?")

But a risk here, for careproviders who follow this New York law, at least to the letter, is that they might give patients more information than they need or want, which may be harmful. It could "overload" them. Astrow and Popp, two physicians, strongly make this point: "What is needed in such cases is not simply information, but an appreciation for the profound anxiety everyone feels at the border between life and death. In asserting power over the way in which deep and troubling human questions should be addressed . . . the New York legislature seems likely only to generate cynicism. . . when . . . patients and their families are most in need of honesty, kindness and engagement."[14] Elderly patients in China, Chan says, have an overriding reason to not want to know that they are dying: they believe if they discuss death, it may have unwanted consequences, even hastening their own death. In the U.S., patients may not want to have this information for other reasons. They may even simply just want to deny it. How hard, under these circumstances, should we "push"? Should we respect patients' denial more than we typically do now in the U.S.?

1. Asking patients how much they want to know. One way careproviders can approach the question of how much patients want to know is to take the initiative to ask. This may be the best approach, but there is a risk that if patients don't want to know, and no one asks them whether they'd want to know if they are dying, it may let the "cat out of this bag."[15] If patients haven't discussed it, and no one asks, the patients' preferences can only be inferred.

Adult children in or from China might have greater moral justification than we would in the U.S. for inferring that a parent would want them to decide whatever they think is best, since this is, as Chan tells us, already a common value for them. Recent research on "giving bad news" indicates that patients in the U.S.—as within any culture—differ. Some want all possible information, but many want less. The latter group may not want to know, for example, how much longer they are likely to live.[16] And while some patients want all of the information they can get, as soon as they can get it, others want it in smaller doses, over time.

In general, patients often want specific information on how their terminal illness is likely to affect them. In providing this information, careproviders may want to avoid using vivid visual images, because these may be remembered differently than more abstract, verbal concepts. For instance, visual

images, if presented as "worst-case scenarios," may continue to "haunt" patients to a greater extent.

Like all of us, patients may not know what they really want. For example, patients may feel, at first, they want all possible specific information, but later may feel they want only more general information.[17] Given the different needs of different patients, and given that patients' needs may change over time, perhaps the best way to meet patients' needs is to say, each time, after providing some new information, "Is this enough information for you, for now?"[18] This may be an optimal way for careproviders to provide information that leaves the decision of "how much information?" wholly up to patients.

If careproviders suggest to a patient who is seeking information, "Let's wait until later," the patient may feel pressured respond, "OK." It is important for patients to have all the control that they can, especially when they lack control due to a terminal illness. When careproviders want to advise waiting until later to provide information, at most they might suggest, "Perhaps it might be wise to wait to discuss some more specific questions until a later time, because, right now, it is most likely that they will never arise. What do you think?"[19] Careproviders could share this further rationale: "If we discuss this now, and these concerns never do arise, our discussing these concerns now will cause you unnecessary worries."

Alternatively, careproviders could opt to give a patient more information only when he or she asks for it. This approach, however, has a downside: it may discriminate, in its effect, between patients who ask for information and those who, for some reason or other, don't ask. It may not be ethically justifiable to discriminate between the two groups, based on this difference.

2. Giving patients hope. When and the degree to which careproviders should try to convey hope may, for somewhat analogous reasons, differ among patients. Some patients may still want all possible information, even when there is "no hope for cure," and they may lose trust in their careproviders if careproviders don't openly tell them everything they can. Careproviders who seek to overcome this risk could urge patients to feel "other kinds of hope," such as hope that the patient can leave a good memory with others, or of dying with dignity. For some patients, hope that they won't be soon dying, though, is the only kind of hope they want. Careproviders who know this may give hope in some ways that are literally truthful and yet allow such hope. They may tell a patient, for example, that some patients "defy the odds." Still other patients may want a hope of a cure, yet want the truth—that will destroy this hope—*at the same time*. Careproviders' task may then be paradoxical.[20] For example, a patient was dying of cancer. He told every careprovider he saw that he wanted all possible information. He later told me he'd "quit" his oncologist because he asked him what he could do to prolong his life, and this oncologist had said truthfully but bluntly, "Nothing."[21]

Of Mexico, and of the Kindness of Strangers

In this issue of *JCE,* Joshua S. Baru, Brian P. Lucas, Carmen Martinez, and Daniel Brauner describe their study of 59 hospitalized men who were "undocumented, Hispanic immigrants" in "Organ Donation among Undocumented Hispanic Immigrants: An Assessment of Knowledge and Attitudes."[22] First, the authors asked the respondents whether they would be willing to donate an organ to a stranger. Then, the authors told the respondents that if they needed an organ transplant in the U.S., they most probably wouldn't get one. Finally, they asked the respondents whether they would still be willing to donate an organ to a stranger. Three-quarters said they still would. This finding has important implications for careproviders for two reasons.

First, it exemplifies how the respondents in the study would extend their altruism beyond family members and good friends. Some might see this as going beyond what a person should be willing to do. That these men said they would be willing to extend such a gift to strangers may, however, represent a more ethically enlightened, *global* perspective to which, now, we all should aspire.[23] That many in the U.S. and elsewhere feel the same way as the men in this study is, at the very least, something careproviders should know. This awareness could, in some cases, change what careproviders do here in the U.S.[24]

Second, these findings suggest that our willingness to give to others is not based in reciprocity, as many believe. The principle of reciprocity is used in game theory to understand how people may act to benefit themselves maximally, especially over the longer run.[25] Reciprocity may be used to support many clinical judgments, for example, when a mother agrees to undergo fetal surgery mostly for the sake of her fetus, or when family members continue to care for a loved one even though it causes them emotional or physical harm. When a person chooses to give without an expectation of reciprocity—like the Hispanic patients who said they would donate an organ if it was needed, with no expecta-

tion of receiving a donated organ, if needed—we may respect their gift more than one made with the expectation of some kind of repayment.

Third, the responses of the Hispanic men have far-reaching implications for careproviders who treat patients "eye to eye." That is, when careproviders tell patients an unpleasant truth, it may *not* damage their relationship with patients. When careproviders are honest and forthcoming, it may strengthen the relationship. It is something most patients will deeply appreciate.

For example: some hospitals require its mental health careproviders to obtain a signature on a "no-suicide contract" from suicidal patients, even though there is evidence that this policy may be quite harmful, overall, because patients may feel "distanced" when careproviders ask them to sign, and so they may be more likely to commit suicide. One of my colleagues had a patient who balked at signing such a contract. He asked, "Why?" My colleague replied that she guessed the hospital required her to request a signature because the hospital thought it would be better, legally, to protect *itself*. She said she disagreed and thought it was harmful to patients. The patient thanked her profusely for telling him this. He said that this caused him to trust her even more.

Of the U.S., and of Those Who Are Most Alone

In "Surrogates and Extra-Familial Interests," in this issue of *JCE,* Ralph Baergen and William Woodhouse consider the case of a patient who has physical and cognitive impairments that are most likely due to a brain tumor that could be removed.[26] The patient has been confined to a wheelchair and has lived in an institution for years. If the tumor is removed, the patient may become legally competent, and be able to resume independent living. If he can, though, there is a problem: he has a history of pedophilia, and he may resume being a danger to children. The patient's sole living relative is a younger sister, who has children. She is afraid that if she takes "responsibility" for him, he may harm them, as he harmed her when she was a child.

This case raises a number of important issues. First, there is a concern for the sister that may not be obvious: she could make the difference in whether or not the patient gets surgery. If she doesn't consent to it, will she suffer a great deal of guilt? Others who have another's fate in their hands may suffer in this same way. Thus, one concern is whether, in some way, the greater society should try to attend to this difficulty. That is, is there some way that society can take responsibility for such patients, so that when a family member can't take responsibility—in this case, the sister was asked to approve the surgery and arrange for supervision for the patient afterwards—society can? This approach extends our caring for loved ones to caring for strangers—like the men from Mexico, who said they would be willing to donate an organ to a stranger.

A second, greater question is how anyone could possibly consider not providing surgery to this patient, when it seems likely that surgery would help restore his competency and his "freedom." Typically, in our society, we do not hesitate when surgery could restore a patient's mental capacity. We typically do all that we can to help patients. Perhaps, in part, for this patient, some of us might not provide surgery because it would it allow us to remain *passive*.

That we may find it easier to remain passive in morally stressful situations is explored in a well-known thought problem called the trolley question. A trolley is headed toward five people on the tracks, who are tied up and unable to move. You are next to a lever, some ways away, and, by pulling the lever, you can make the trolley switch to a different set of tracks and avoid the five people up ahead. But there is one person stuck on the other track. Which option will you pick: do nothing and allow five people to be killed, or pull the lever and allow one person to be killed?[27] Research indicates that most of us would find it more difficult to actively pull the lever and kill another human being, regardless of the number of lives it would save. Studies using f-MRI brain imaging report that a new part of research participants' brains lighted up when they considered how, to act morally, they should actively respond in such situations.[28]

But, as a society, it is abhorrent for us to even merely consider not providing surgery to the patient in the article by Baergen and Woodhouse. Such a response is the opposite of what Ed Pellegrino would have prescribed: taking right initiatives when we should. A broader, more invidious implication, however, is that we might be discriminating against others without being aware of it.

Why might we find it so easy, in this instance, not to act? The answer is, for me, personally painful—and it should be—because my first reaction when I read this case was to think of the welfare of the patient's sister and her children: What would most benefit them, or do them the least harm? I probably felt negatively toward the patient because of what he had done. Based on this, it makes sense to ask ourselves how often we prejudge others, based on our own visceral responses to them, without knowing we are doing this.

Here is another example of how stigma may blind-side us to our own biases, from a recent annual meeting of the organization concerned with human research protections in the U.S. It concerns research now being conducted strictly according to U.S. policies on protecting research participants.

Great human suffering is created by persons' addictions to various chemical compounds. A current attempt to mitigate the power of addictive substances is to find a medication that lessens the pleasant effects of these substances. Researchers need to test the effectiveness of medications with human participants, but since the participants must use the new medication in combination with the addictive substance—for example, cocaine—there is a danger that participants who have not used the addictive substance previously may become newly addicted through its use during the research study. So researchers seek out participants who have used the addictive substance before.

But researchers also need to recruit participants who are "clean," that is, who state they are not currently using the addictive substance, and test accordingly. Another criterion is that participants must state that they currently, genuinely, aren't interested in treatment, because it would be wrong to not give participants treatment if they did want it, and the research does not currently include treatment.

At this major research meeting, one presenter, Edward Nunes, reported on a small study in which people who were not current users of an addictive drug were given a medication called ketamine, used as an anesthetic.[29] Ketamine recently has been found to profoundly reverse some patients' depression, but it is only effective for a short time. In this study, "former" drug users who had previously said they did not want treatment for their addiction were given ketamine. Some cried. Some expressed, for the first time, how much they regretted their previous drug use, and that they wanted to change.

David Strauss, Nunes's co-presenter, asked whether we too easily believe participants in addiction studies when they say they do not want treatment. On some other level, beyond their awareness, perhaps they do. Strauss is concerned that we too easily accept what these research participants tell us about not wanting treatment, possibly because we have negative attitudes toward them, based on their past drug use. Both Strauss and Nunes suggest, as a different, ethical approach, that we add treatment components to current "nontreatment" protocols, such as motivational interviewing.[30]

Could such a possibly negative view of people with addictions bias our judgment, without our knowing, so strongly that we can act invidiously, as individuals as well as members of a whole society? In the same way, is it possible we have a negative bias against people who abuse children sexually, such as the man with the brain tumor who needs surgery? Such people are among those who are most alone. Considering these things can add a great deal to the number of things that we *might* do to help them. Edward H. Khantzian, a psychiatrist, says what in our lives is "worst" is not that we can suffer. What is worst, he says, by far, is that we can suffer *alone*.[31]

"ED PELLEGRINO'S CASE"

The case I asked Ed about was the following real one. A small group of civilian careprovider volunteers were staffing a medical clinic in a rural area of a foreign country. A man who lived in this rural area brought in his teenage daughter who needed immediate, lifesaving surgery. The man said that his daughter could only have the needed surgery if the surgeon was female. Unfortunately, there was only one, male surgeon at the medical clinic.

The staff had heard about a similar situation at a rural clinic not far away. There, a man brought in his daughter, whose body and face were badly burned. The father forbade any male careprovider to be in the operating room while his daughter was in surgery. Their only surgeon was male, and he performed the operation. The staff told father this. The daughter survived surgery, but, when she was released, the young woman's family killed her, throwing her out of the car when it was going full speed.[32]

The law in this country proscribed this, but crimes like this continued to occur.

The staff in the case I presented to Ed performed the surgery behind closed doors, and then lied to the father about who had been in the operating room during surgery. Ed said he would not have lied. He said that he believed in discussion based on mutual respect. When moral views are in conflict, he wrote, "some extensive dialogue is in order."[33] This approach of "respect and negotiate" is, generally speaking, the expected "first rule," and Ed's skills at this were second to none.[34]

Ed did not say, after saying he wouldn't choose to operate and lie, what he would do if this failed. I suspect he would have called in the local authorities to protect the daughter, and, thereafter, to do whatever was necessary to continue to protect her life, even if this would have meant bringing her back to the U.S., and even though this would have ripped her from her culture and all of the family and friends she had known.

Ed wrote that "never killing" was the "most fundamental" of all of the absolute moral values, although "never lying" was important, as well. "Deception," he said, "leads to mistrust and anger when the truth becomes known, as inevitably it will be." He wrote, too, about the current "international scene," and stated, in regard to it, that the "inherent dignity" of all humans is the moral foundation of what we owe to each person.[35]

I suspect Ed's success in negotiating ethical conflicts with patients might have been due, in no small part, to his integrity, which was apparent to others. For example, he said that in decades of clinical practice he had never asked a patient to accept being treated by a student he was supervising and had the patient refuse. This position, to respectfully negotiate, he shared at USUHS with literally thousands of students. When these students now ask their patients whether they can do procedures "on" them, rather than presume they have permission, as most careproviders almost always do, this may be due to Ed.

CONCLUSION

This introduction focused primarily on Ed Pellegrino, on three different cultures, and what they might teach us. In her article, Chan describes how Chinese and Chinese-Americans hold their family members in high regard. We may find ways to do this more, here. We might do more to help patients who are at the end of their lives to do what their families want, if this is what the patients want. We might be less concerned when, having told patients the truth that they have a fatal illness, the patients act in ways that suggest they are denying this.

Baru and colleagues report that a majority of the Hispanic men they interviewed said they would donate an organ to a stranger, and that most of the men would do this whether or not they would be able to receive an organ transplant in the U.S. These men model altruism to which we all should aspire. Their willingness to donate, even after careproviders told them they probably would not receive an organ transplant if they needed it, indicates that careproviders may earn additional trust from their patients when they speak frankly with them.

Here in the U.S., Baergen and Woodhouse considered the possibility of not treating a man who needed brain surgery, who had a history of sexually abusing children. Perhaps it seems easier to do nothing for him, to remain passive, due to a society-wide moral blindness that exists beyond our awareness, based on bias against persons who harm children. Such considerations raise new questions regarding our treatment of family members, strangers, and those who are most alone.

At the recent annual meeting of the American Society for Bioethics & Humanities (ASBH), outgoing society president Joseph J. Fins spoke of Ed Pellegrino as being like the renowned physician, Sir William Osler.[36] In this issue of *JCE,* in "On the *Lingua Franca* of Clinical Ethics," Fins describes a case in which he asked a patient whether she would want to be "put under" general anesthesia for a week to see if her lungs might heal.[37] This was what Ed would have done: asking and doing what he believed would be medically best for his patient. At this ASBH meeting, Fins, with a colleague, discussed how they respond at Cornell when patients and families want treatments that might be considered futile. They explained that they don't label treatments as futile, rather, they *negotiate* with patients and family members. They negotiate as long as they can, and only make a decision, if they must, for the remaining "1 percent."[38]

This is Ed.

NOTES

1. E.D. Pellegrino, "Intersections of Western Biomedical Ethics and World Culture: Problematic and Possibility," *Cambridge Quarterly of Healthcare Ethics* 3 (1992): 191-6; E.D. Pellegrino, P.M. Mazzarella, and P. Corsi, *Transcultural Dimensions in Medical Ethics* (Hagerstown, Md.: University Publishing Group, 1992). See, also, T.L. Beauchamp, "Does Ethical Theory Have a Future in Bioethics?" *Journal of Law, Medicine & Ethics* 32, no. 2 (2004): 209-17.

2. I should acknowledge, here, on this 25th anniversary of *JCE*, my exceptional appreciation of Dr. Paul Beeson. Dr. Beeson wrote for us a most positive description of *JCE* for subscribers, prior to its publication. He was the author of a leading textbook in internal medicine at the time

3. J. Glover et al., "A Model for Interschool Teaching of Humanities During Clinical Training" *Journal of Medical Education*, 59 (July 1984): 594-6.

We hoped to put our resources together to offer medical students a fourth-year elective in which they would spend one week learning ethics at George Washington, Georgetown, and Howard University in D.C., and at the Uniformed Services University of the Health Sciences (USUHS) in Bethesda, Md. This rotation did come about and lasted for years. We went, then, in pairs, to other cities to share with other schools how they, too, might do this, but, to my knowledge, no other schools did.

4. K.C. Chan, "Challenges to Culturally Sensitive Care for Elderly Chinese Patients," in this issue of *JCE.*

5. H.P. Lefley, "Cross-Cultural Perspective of Family Psychoeducation," *Psychiatric Annals* 42, no. 6 (June 2012): 236-40.

6. Children who know the most about their families seem to have greater self-esteem. They can understand their difficulties in the context of their larger family system, and develop, as a result, a "more nuanced and less harsh" understanding of the challenges they face. A.M. Heru, "Families in Psychiatry: Narratives and Transmission of Resilience," *Clinical Psychiatry News* 6-7, no. 9 (September 2013): 641.

7. A. Crawford, "Sleeping Infants Still Know When Mom and Dad Are Fighting," *Smithsonian* 44, no. 6 (October 2013): 20.

8. J. Greene, *Moral Tribes* (New York: Penguin Press, 2013), 152-3.

9. They also do not know, of course, whether research or the standard of care will be better, because there is clinical equipoise: those careproviders who are the most expert are uncertain.

10. J. T. Berger, "Patients' Concerns for Family Burden: A Nonconforming Preference in Standards for Surrogate Decision Making," *The Journal of Clinical Ethics* 20, no. 2 (Summer 2009): 158-61, p. 158; J.T. Berger, "Patients' Interests in their Family Members' Well-Being: An Overlooked, Fundamental Consideration within Substituted Judgments," *The Journal of Clinical Ethics* 16, no. 1 (Spring 2005): 3-10.

11. Policy and practice, here, might be inconsistent. This might, however, bring about the optimal end result. An example illustrating how this can be is having speed limits not strictly enforced: the speed limit may limit speeding, while the lack of enforcement frees police to do something else.

12. In this case, that the wife and family arrived at a decision that all could accept was additionally important because there were grandchildren. In other contexts, too, family members' interests may warrant moral weight. See James Lindemann Nelson's "Familiar Interests and Strange Analogies: Baergen and Woodhouse on Extra-Familial Interests," for example, in this issue of *JCE*.

A current example, for instance, involves children who need scarce resources, such as drugs to treat their cancer, that are in too-short supply. After other criteria, such as medical utility, are exhausted, negative effects on *other* family members may be among the additional criteria that are considered.

13. N.Y. Pub. Health Law § 2997-c (Consol. 2013), AKA the "Palliative Care Information Act." Discussed at a presentation by L.B. Solberg, "Empowering Terminally Ill Subjects through the Informed Consent Process," at the Advancing Ethical Research Conference, jointly sponsored by PRIM&R (Public Responsibility in Medicine and Research) and Boston University in Boston on 9 November 2013. I wish to thank Lauren B. Solberg for alerting me to this issue and providing me this citation.

14. A.B. Astrow and B. Popp, "The Palliative Care Information Act in Real life," *New England Journal of Medicine* 364 (19 May 2012): 1885-7, p. 1887.

15. Should careproviders or family members ask patients whether they would want to know if there are dying, it may convey to patients that they soon will die. Even when patients say, in reply, "No, I don't want to know," they may sense, thereafter, that careproviders or loved ones are keeping information from them. This may diminish their trust, and then all involved may be carrying on a charade.

Care providers and family members may avoid this risk by asking such questions early enough that they do not know patients' diagnosis or most likely outcomes. L. Van Vliet et al., "When Cure is No Option: How Explicit and Hopeful Can Information Be Given? A Qualitative Study in Breast Cancer," *Patient Education and Counseling* 90 (2013): 315-22, p. 319.

Careproviders who plan to disclosure such information should always ask who, if anyone, these patients would want to have with them. Ibid. See, also, P. Kirk, I. Kirk, and L.J. Kristjanson, "What do Patients Receiving Palliative Care for Cancer and their Families Want to be Told? A Canadian and Australian Qualitative Study," *British Medical Journal* 265 (2004): 1343-9, p. 1347. Patients may prefer that a careprovider disclose information to them alone, or to when they are with their family, or they may want to have a loved one, *not a careprovider*, be the first to share this with them. S.J. Marwit and S.L. Datson, "Disclosure Preferences about Terminal Illness: An Examination of Decision-Related Factors," *Death Studies* 26, no. 1 (January 2002): 1-20, p. 5.

16. Patients who want more information tend to be young, male, well-educated, from a rural background (perhaps because they are more familiar with death and are not religious.) Marwit and Datson, see note 15 above, p. 13. These patients may also be more comfortable with receiving more information when they have social support and tend, as a style of coping, to "monitor" as opposed to to "blunt" threatening information. Since news of imminent death is so unique, the role that these factors play may, in this particular context, still be uncertain.

On the other hand, patients may want and do better with more information when they have had a prior positive experience with death. Thus, careproviders should take a prior psychosocial history to determine this. Ibid., 5. It may be, also, that patients with less education tend more to favor having their families with them when careproviders inform them. Ibid., 15-16. In any case, careproviders have, it appears, tended to err by choosing too often to disclose such information to patients *alone,* without asking patients whether this is what they want. The effect has been to "delegitimize" the presence of these patients' families, thus denying these patients and families what they may most need and want. Ibid., 15.

As Chan points out, Chinese parents may feel more comfortable, though, talking with people who are *outside* of their immediate family. This may, be for example, because they sense, perhaps rightly, that their family members feel too close to them, and, thus, these discussions could be too painful for them. Chan, see note 4 above.

One mother from Australia who had cancer said, in regard to her children, for example, "what I haven't done is asked them . . . what's going to happen . . . I think they've taken it, in a sense, a lot harder than me . . . all I'm going to do is die. They've got to watch me die and then get on without me." Kirk, Kirk, and Kristjanson, see note 15

above, p. 1348.

As this may be the case, careproviders might specifically ask patients whether, in addition or instead of sharing what they are feeling with only their families, they might also want the opportunity to speak on an ongoing basis with others, *outsiders*, who are not so involved.

17. J.R. Curtis et al., "An Approach to Understanding the Interaction of Hope and Desire among Individuals with Severe Obstructive Pulmonary Disease or Advanced Cancer," *Journal of Palliative Medicine* 11 (2008): 610-20.

18. Van Vliet et al., see note 15 above, p. 319. Currently, in response to this difference among patients that careproviders can't anticipate, many careproviders respond by what is called "pacing." They give out information gradually, over time. Kirk, Kirk, and Kristjanson, see note 15, above: "it is important to provide info on a regular basis, shift from 'cure' to 'palliation'," (p. 1343). It is unclear whether whether it is preferable, when careproviders tell patients how long they can expect to live, whether providing qualitative words or specific numbers is preferable. Van Vliet et al., see note 15 above, p. 315.

19. Van Vliet et al., see note 15 above, p. 318.

20. "Dependent on the meaning of hope for an individual, a paradox may exist if they also desire realism. . . . This paradox . . . may present one of the biggest challenges for professionals." S. Innes and S. Payne, "Advanced Cancer Patients' Prognostic Information Preferences: A Review," *Palliative Medicine* 23 (2009): 29-39, p. 36. Careproviders can give some patients hope by taking the initiative to point out ways in which patients and their families, for a time, can continue to live fully, if, and only if, this is actually the case. Van Vliet et al., see note 15 above, p. 317. In some case, this may involve careproviders pointing out what neither the patients nor their families have imagined. Patients may perceive this, however, as their careproviders not understanding the depth of their despair and/or, thus, their lacking in empathy. Careproviders may try to tailor their responses to the patients' and families' unique needs, using their intuition. This may, though, require greater interpersonal sensitivity than many careproviders are able to offer. Ibid., p. 319. Moreover, even when careproviders have most exceptional interpersonal sensitivity, being able to intuit accurately what others want may be beyond what even then they can do. Ibid., p. 319.

21. At the 15th Annual Meeting of the American Society of Bioethics & Humanities (ABSH), just concluded, Irene Ying, a physician, reported on three brain-imaging studies that suggested three *different* ways in which our brains may create denial, suggesting that this response maybe one acquired through evolution, because it is *adaptive*. She suggested, making clear that she was speculating, that patients may be able to both know that they are dying, but deny this, at the same time, so that it may be that careproviders should accept this more than they do now. I. Ying, "Therapeutic Doublethink: A Novel Concept to Ethically Justify Unrealistic Optimism in Patients with Advanced Cancer," presentation at the 15th Annual Meeting of the American Society of Bioethics & Humanities, held 24-27 October 2013, in Atlanta, Georgia. It is well-known by careproviders who are familiar with hypnosis that people can hold contradictory, mutually exclusive beliefs at the same time. The contradiction, when in a trance, simply doesn't concern them.

22. J.S. Baru, B.P. Lucas, C. Martinez, and D. Brauner, "Organ Donation among Undocumented Hispanic Immigrants: An Assessment of Knowledge and Attitudes," in this issue of *JCE.*

23. "Altruism . . . eventually branched out beyond close relatives. . . . [Environmental stress is] not devoid of bonding power." R. Wright, *Nonzero*: *The Logic of Human Destiny* (New York: Vintage Books, 2000), 324 and 328. James Doty, a neurosurgeon, has founded and directs the Center for Compassion and Altruism Research at the Stanford Institute for Neuro-Innovation and Translational Neurosciences in Stanford, Cal. Strengthening our "compassion muscle," he says, to include "out-groups" throughout our globe is "how humanity is going to survive." E. Svoboda, "The Selfish Benefits of Compassion," *New Scientist* 220, no. 2939 (19 October 2013), 28-29, p. 29.

24. Transplant teams "have generally been suspicious" of living donors donating to strangers but "a majority of the public believe this is right." T.L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics,* 7th ed. (New York: Oxford University Press, 2013), 55. See, also, A. Spital and M. Spital, "Living Kidney Donation: Attitudes Outside the Transplant Center," *Archives of Internal Medicine* 148 (May 1988): 1077-80; and C.H. Fellner and S.H. Schwartz, "Altruism in Disrepute," *New England Journal of Medicine* 284 (18 March 1971): 582-5.

25. D.L. Cohen, "Not Playing Games," *American Bar Association Journal* 99, no. 1 (January 2013): 25-6.

26. R. Baergen and W. Woodhouse, "Surrogates and Extra-Familial Interests," in this issue of *JCE.*

27. For a current overview and summary of studies in this area, see Greene, note 8 above, pp. 113-21.

28. J.D. Greene, R.B. Sommerville, L.E. Nystrom, and L.E. Darley, "An fMRI Investigation of Emotional Engagement in Moral Judgment," *Science* 293 (2001): 2105-8.

29. E. Nunes, "Panel X: Giving Drugs to Drug Users and Other Ethical Quandaries in Research on Substance Use," presentation at the Advancing Ethical Research Conference, jointly sponsored by PRIM&R and Boston University, Boston, on 9 November 2013.

30. D.H. Strauss, "Panel X: Giving Drugs to Drug Users and Other Ethical Quandaries in Research on Substance Use," presentation at the Advancing Ethical Research Conference, jointly sponsored by PRIM&R and Boston University, Boston, on 9 November 2013.

31. E.H. Khantzian, "We Are All at Least a Little Lost and Off-Putting: On Transformation," *Psychiatric Times* 30, no. 11 (November 2013): 37.

32. Young women in forced marriages who feel hopeless may commit suicide by self-immolation. H. Turner, "Literature Review: Afghanistan Women's Health Crisis, Health Service Delivery, and Ethical issues for International Aid," *Health Care Women International Journa*l 27, no. 8 (September 2006): 748-59, p. 751. How many, if any, of these suicides are, in fact, murder, made to look like self-immolation, is open to conjecture. In 1997, six million Afghans had no access to medical care. Ibid. Touch

between men and women may be prohibited, and even the use of interpreters of the same sex is recommended. Ibid., 754. "Humanitarian aid . . . may be all the medical care [these] people in some contexts . . . get." Ibid., 756. Doctors without Borders lost five staff in June 2004. They were shot and killed on a road. Ibid., 756-7.

One local person said, "It is better that one person dies than the whole family of shame and disgrace. It is like a box of apples. If you have one rotten apple, would you keep it or get rid of it? I just got rid of it." R. Husswini, *Murder in the Name of Honor* (Oxford, U.K.: One World Publications, 2012), 10.

Most honor killings occur in poor and uneducated populations where word of mouth spreads fast, and in rural populations, where economic hardship and daily struggles are the "rule of the day." Ibid., 43.

33. D.C. Thomasma and E.D. Pellegrino, "The Role of the Family and Physicians in Decisions for Incompetent Patients," *Theoretical Medicine* 8, no. 3 (October 1987): 283-92, p. 285. "The difference between our view and that which argues for an absolute respect for patient wishes is that ours more explicitly rests on a dialogue about values." Ibid., 287. "The family can be seen as the object of the value the family holds. . . ." Ibid., 287. "Our unconventional view of patient autonomy . . . incorporates respect for patient values logically prior to respect for current wishes or free actions." Ibid., 290. Would this girls' prior values have included her preferring to die rather than to have a male surgeon operate? A Jehovah's Witness patient might prefer death, but, then, this should be that patient's view, not one imposed by a parent.

34. Building new relationships and non-coercive responses, rather than using power and coercion, enables people "to break out of the defensive private shells into which they [have] retreated, often out of fear." H. Miall, O. Ramsbotham, and T. Woodhouse, *Contemporary Conflict Resolution*, 3rd ed. (Cambridge, U.K.: Polity Press, 2011), 40-4 and 53-4.

35. E.D. Pellegrino, "Some Things Ought Never Be Done: Moral Absolutes in Clinical Ethics," *Theoretical Medicine and Bioethics* 26 (2005): 469-86, pp. 475, 480, 481, and 483. Ed dedicated this article to the memory of his colleague, David Thomasma. "I do not know whether he would have agreed with this approach," Ed wrote. "But I do think he would consider a proposal for a modest retrieval of moral absolutes possible," (pp. 470-1).

36. J.J. Fins, "A Tribute to Edmund Pellegrino and His Work," plenary session at the 15th Annual Meeting of the American Society of Bioethics & Humanities, held 24-27 October 2013, in Atlanta, Georgia.

37. J.J. Fins, "On the Lingua Franca of Clinical Ethics," in this issue of *JCE.*

38. J.J. Fins during discussion, E. Meltzer and N. Ivascu, "Extracorporeal Membrane Oxygenation in Adults: A Primer for the Clinical Ethicist," presentation at the 15th Annual Meeting of the American Society of Bioethics & Humanities, held 24-27 October 2013, in Atlanta, Georgia.

Clinical Ethics at 25 Years

On the *Lingua Franca* of Clinical Ethics

Joseph J. Fins

ABSTRACT

In this 25-year retrospective on the state of clinical ethics, and the anniversary of the founding of *The Journal of Clinical Ethics,* the author comments on the state of the field. He argues that the language of bioethics, as used in practice, seems dated and out of touch with a clinical reality marked by emerging technologies and the advent of new fields like palliative medicine.

Reflecting on his experiences as a clinician and clinical ethicist, the author worries about the emergence of a shallow bioethics, which is the product of a *lingua franca.* This linguistic amalgam is a weak composite in which concepts are simplified and nuance is overlooked, leading to interpretative errors. The best of ethical reasoning or clinical decision making can be lost in translation. Instead of the well-worn arguments over the relative worth of modes of ethical analysis, like principlism or pragmatism, the author argues that the emphasis should be on the cultivation of the "linguistic" skills necessary for translating any critical method in order to replace the lingua franca of clinical ethics with a more substantial discourse worthy of the complexity of the clinic. Through the emergence of such a shared language, at the interface of the sciences and the humanities, this multidisciplinary field can evolve towards more authentic interdisciplinarity.

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Declensions sang on air like a *hosanna*
As, column after stratified column,
Book One of *Elementa Latina*,
Marbled and minatory, rose up in him.
—Seamus Heaney, "Alphabets"

TIME BEFORE HISTORY

Two thousand fourteen is a year of anniversaries, personal, professional, and editorial. Twenty-five years ago I was concluding my residency in internal medicine and starting a stint at the Hastings Center as a visiting fellow. The center had just published its *Guidelines on Care at the End of Life,*[1] and I was beginning to think about clinical ethics, usually with that volume at my side. And for the readership of *The Journal of Clinical Ethics,* 2014 is the twenty-fifth anniversary of its founding.

Silver jubilees are occasions for reflection. Enough time has gone by to gain some perspective, yet the story is too ripe for the disinterested pen of the historian. The moment still belongs to those who helped create the recent past, providing one last chance to get it right, to confront legacies that may have introduced unintended contradictions into our thinking and practices.

It also a time to reflect on the demographics of the practice space. The philosophers and theologians who originally inhabited the space have been augmented, indeed nearly replaced with clinical personnel who are more pragmatic in orientation. New

technologies have challenged old formulations about withholding and withdrawing life-sustaining therapies that were designed for "simpler" times. The broader context of care has also changed. With the burgeoning of the palliative care movement, the clinical ethicist's niche has become one of co-habitation and, even, peaceful coexistence.

These developments warrant systematic reflection, and I hope to start that process here. I think clinical ethics needs to rethink some long-held "truths" to maintain our relevance and to augment our potential for meaningful contributions in a fast changing clinical context. You may agree or disagree, and on behalf of our editorial board, I invite you, the reader, to join in the conversation. Submit your commentaries to *Clinical Ethics at 25 Years,* a column that we will highlight during this year. Let's use this milestone to improve on what we have wrought.

The historians will come soon enough.

LANGUAGE OF BIOETHICS

Sometimes, as I walk the wards doing an ethics consult, I feel as if I am speaking an ancient language, like the traveler in modern Europe who only knows Latin. Traveling from Italy to France and on to Spain, the sounds are familiar, but communication is difficult. There is a familiarity to what is heard, but being understood is a different matter. Although the cognates are known, the tense is off. The idiom has become more dynamic and the language of the clinic more specific. Something invariably gets lost in translation.

So too when I talk about clinical ethics to my clinical colleagues. They question settled norms and constructs and seem to misunderstand what we, in clinical ethics, accept as consensus views. Increasingly, much of what we discuss as clinical ethicists seems out of step.

At least to my ears, the language of clinical ethics has lost its agility, if it ever possessed it. It has become something of an ancient language, one that is read and debated in seminar halls fading from the vernacular of the hospital wards. Why? Because the guiding grammar that informs clinical ethics has become a relic of principlism, a method of moral problem solving that is too nonspecific to provide practical guidance in complex cases. Although an elegant theoretical approach, its applicability to clinical practice has weakened, even as newer editions of Beauchamp and Childress's venerable text, *Principles of Biomedical Ethics,*[2] have been modified to become more accessible to clinical audiences.

This should not come as a surprise, as principlism was not intended to be a method of analysis for clinical ethics. Its origins were not in the clinic, but in research ethics, and the "common morality" that informed *The Belmont Report*.[3] Yes, we want to foster autonomy, avoid harm, and promote the good, all the while being fair and just. But can we do all that at the same time, given the mix of factors that complicate the clinical context? And if one principle conflicts with the other, which one prevails?[4]

Beauchamp and Childress have written of the balancing and specification of principles as a means to make these judgments. Others like Jonsen, Siegler, and Winslade have taken a strikingly different approach, seeking to reach moral judgments after collecting and analyzing data from the bottom up.[5] Although DeGrazia has astutely noted that moral reasoning in principlism is not invariably downward but can move from particular cases to general principles under what has been described as a coherence model of ethical justification,[6] there is no doubt that one is primarily deductive (Beauchamp and Childress) and the other inductive (Jonsen et alia).

The "four topics approach" of Jonsen, Siegler, and Winslade is an evidentiary method that reviews the particulars of medical indications, patient preference, quality of life, and contextual issues before reaching a judgment. It is focused on the details and nuance of each ethical quandary and seeks to reach particularistic judgments drawn from the facts of the case. If principlism is more akin to appellate legal reasoning, the four topics approach resembles what occurs in a trial court, where adherence to due process leads to presentation of evidence necessary for reasoned judgment. Appeals are reserved for incomplete or flawed process or questions for which no true consensus exists.[7]

My own efforts in case analysis have been in the tradition of Jonsen, Siegler, and Winslade[8] and more proximally, the late John Fletcher,[9] all of whom can be loosely categorized as being in the American pragmatic tradition. Following their good example, I have spent much of my career trying to operationalize an inductive method of moral reasoning that my colleagues and I called *clinical pragmatism*.[10]

Based on Dewey's theory of inquiry, and like clinical practice itself, clinical pragmatism starts with the recognition of a problem, a problematic situation, to start a process of analysis.[11] This process of inquiry collects narrative, clinical, and contextual data to build an "ethics differential diagnosis," a range of reasonable—yet contingent—hypotheticals to be validated through practice. It is a bottom-up approach that accommodates novelty, detail, and

uncertainty, but leads to principled decision making.

Although I am gratified by those who employ clinical pragmatism in their practices, the dominant school—in the clinic and, *as importantly, in the law*—remains principlism, not these more pragmatic approaches. I believe this has come at a cost, decreasing the avidity for clinical ethics in the clinical sphere, where diagnostic reasoning is itself inductive.

AUTONOMY AT LIFE'S END

If we consider decisions to withhold or withdraw life support, we will quickly see how principlism is out of step with a major focus of clinical ethics and its deliberations. And it is here, at the end of life, when the dominant principle of autonomy, most forcefully expresses itself.

Despite the explosion of new technology and means of life support, the clinical ethicist's discourse still treats resuscitation as if it amounted to basic cardiac life support (BCLS) and an earnest bystander providing cardiopulmonary resuscitation, alternating chest compression with mouth-to-mouth breathing. Despite the veritable arms race of medical technology that is overwhelming intensive care—and requires more specific guidance and nuance—the basic ethical and legal frameworks for these decisions were drawn up decades ago.

And while BCLS has been supplanted by advanced care life support (ACLS), we still talk of "making a patient DNR"[12] and forgoing cardiopulmonary resuscitation. Chest compressions and ambu bags are the least of it. What of the drugs, the devices like pacemakers and extra-corporeal membrane oxygenation (ECMO) that now move us beyond acute resuscitation to efforts that seem like chronic resuscitation?

The DNR framework seems to be at the end of its tether for most of the resuscitation decisions we consider, like an attenuated Newtonian mechanics encountering high velocity physics. The analogic thinking only gets you so far, and concepts like being DNR on ECMO boggle the mind. Yes, I suppose that means one would not attempt chest compressions on a patient attached to the bypass machine, but what good would even the most earnest pumping do when the ECMO failed to perfuse and ventilate? Yet many incrementally approach a withdrawal of ECMO by taking the seemingly "intermediate" step of writing a DNR order, which logically should also mean that the ECMO be turned off, as it *is a resuscitative act.*

My point is not to solve the ECMO quandary here—my colleagues and I have recently written about that conundrum[13]—instead it is to point out the need to think about our actions in the clinic in a different way, not so bound up with questions of resuscitation, a physiological refuge that had a patina of scientific neutrality when it was introduced, because it was so binary. One either did CPR or not. Now it's not so simple, and pretending it is lends false reassurance to those who must make complex decisions.

More problematic is the centrality of the DNR discussion. While that was appropriately the center of conversation when we needed to advance the permissibility of the negative right to be left alone, that right is now well ensconced in practice and the law. That has been a notable success of bioethics. But that victory obscures the fact that, in complex cases, the decision is not simply one to forgo care, but to make other affirmative choices, such as those for palliation. The DNR question, so dominant as it remains, distorts the clinical transaction at the bedside and ultimately truncates choices for other care options. As I have written, it is not a comprehensive plan for end-of-life care, but "simply a plan for the last fifteen minutes of a patient's life."[14]

We need to expand and deepen the conversation beyond the mechanics of a DNR form. If we still agree with the importance of choice—and we must—these choices need to be more available and informed. Surrogates will need better explanations of what is being proposed, and we, the clinicians, need to be clearer about what we are doing, ambiguity and all. And perhaps most importantly, the choices have to be real and, I would daresay, *guided.*

In a desire to satisfy a mistaken notion of both autonomy and patient rights, we have allowed families to demand—and receive—care that is futile, if not overwhelming disproportionate, often misrepresenting what clinicians might do as effective when it is not. It is much like the "slow code" of old, in which "show" efforts at resuscitation were performed to satisfy a family's desire for a "full code." Those actions were dishonorable, a breach of physician integrity that misrepresented faux resuscitation as efficacious, when it was known to be ineffective.

Providing ineffective and burdensome care at the behest of surrogates to patients who are no longer able voice a preference seems to me something just short of a slow code. Even though clinicians are revulsed by what they are sometimes called upon to do, and know it will be burdensome and ineffective, they feel obliged to offer "everything," in case

they be accused of misusing their power and breaching the sacrosanct autonomy of the surrogate. In the past 25 years, this deference has undergone a transformation, from hearing surrogates' preferences to being bound by them. I think that we need to restore some semblance of shared decision making so as to avoid such distortions in care decisions.

FUTILITY

So much of what happens in clinical ethics centers around disagreements about appropriate care. The most common variation on this theme is the prototypic futility dispute in which patients' families (they usually occur after the patient has lost capacity) demand care of uncertain or marginal benefit, that clinicians hope to avoid. The plot line is familiar to readers of this journal. . . . Families assert their autonomy and demand care that has no clear benefit, or is, at best, highly disproportionate in its risk versus benefit ratio. Practitioners believe they have explained the hopelessness of the situation,[15] but have actually failed in communicating the direness of the situation with rhetoric that is often obscured by medical jargon.[16] The outcome: Despite the futility or marginal utility or the burden associated with the treatment, care is provided because the value placed on choice allows for some unbelievably bad ones.

When families make such demands, they generally win, drawing authority from the prizing of autonomy and self-determination over other goods and laws that were meant to protect patients and families from the value judgments of clinicians, but that now prevent those same physicians from protecting their patients from disproportionate harms from burdensome treatments without foreseeable benefit. Add to this mix the willingness of many physicians to take a path of least resistance and go along with that extra round of chemotherapy, lest they be the victim of reprisal by malpractice litigation—a phantom that seldom occurs.

When a clinical ethicist encounters this all-too-familiar dynamic, he or she is trained to respect patients' and families' preferences, and to help clinicians educate families about possible outcomes and realistic goals of care, endeavors that work when addressing families who possess a requisite degree of rationality and calm, but those are not the families who generate futility disputes and demand ever more care. For those families, the conventional approach is wholly inadequate, placing clinicians in the position of providing care that they can only describe as inhumane.

While such a perspective can be chalked up to the idiosyncratic sentiments of particular practitioners, this constellation of feelings has occurred too often and too widely to be ascribable to outlier sentiment. Instead, this outcome is reflective of a system of interactions, of discourse, that fails to protect patients from harm and asks clinicians to provide disproportionate care.

Why would an ethical framework allow this to occur? First, because principlism has been so misunderstood in the clinic as simply the primacy of autonomy, an unnuanced acceptance of self-determination, a "the customer is always right" attitude, that pertains to commerce, but not to the professions. This deference to patient autonomy has distanced physicians from their own professionalism and their ability to be self-regulating. Where there should be a corpus of professional knowledge and norms, there is a reluctance to partake of judgment, lest this use of the physician's power be equated with paternalism. So physicians abdicate and do what they perceive they must do, without questioning the family's prerogative to direct care or reflecting upon their judgment. They avoid these essential "second looks" or gut-checks, lest they violate the sanctity of patient autonomy.

The language of bioethics, at least as practiced in the clinic and written in state law and federal mandates like the Patient Self-Determination Act,[17] have too often taken physicians' discretion off the table in futility disputes too. We have come to believe that all such exertions are paternalistic. But as Howard Brody has argued for the ages in his wonderful *Healer's Power,* the practice of medicine is impossible without the exertion of power, of judgment and discretion.[18]

A case in point involved a patient with a terminal malignancy. She had an open sternal wound. Her family demanded resuscitation, and no one dared write a do-not-resuscitate order because, under prevailing state law, a DNR order cannot be written over the objection of a surrogate (the patient lacked capacity). The DNR law's deference to the family circle precluded a formal DNR order that could have protected the patient from cardiac rupture from the shearing forces of a displaced sternum being compressed.

Here, Hippocratic ethics called for the patient's protection from harm, and so the physician and clinical ethicist met with the family and told them that, in the event of a cardiopulmonary arrest, the patient would not receive chest compressions. She would continue to be ventilated by her tracheostomy and receive medications if indicated, but no chest com-

pressions. They did not ask for permission to be relieved of an obligation to perform chest compressions because *it was neither indicated nor safe, and they were willing to make that call.* They invoked their medical knowledge and the power of their medical licensure to make this determination. And when the family asked for *open* cardiac massage, they responded that it was not appropriate and not current practice under these circumstances—in an obtunded, elderly patient with metastatic disease.

Now some readers might view actions taken in this case as an abuse of authority by the doctor and clinical ethicist (who also happened to be a physician). I would argue in their defense that they acted ethically, protecting the patient from harm and appropriately exercising power, overcoming barriers intrinsic to clinical ethics and the law that made this exertion of professionalism difficult.

NOT SO FAST

Even as I read the words I have just written, I wish it were that simple. If all our ills could be cured by a tempering of the family's desires with a dose of professionalism, we could be in the clear. But it is not that simple, because what passes for professionalism too often reeks of ideology, a self-satisfied sense of righteousness that is neither critical nor reflective.

I worry too that a call for a resurgent physician voice could create an opening for a new sort of paternalism, flying under the progressive flag of a second wave of palliative care. What do I mean by that? Well, I am concerned that palliative care—as a construct and a practice—has become too prescriptive and ideological, advancing a proscribed way to die. It has morphed from a prizing of patient choice and a means to maximize the quality of one's remaining days, to a decision to withhold or withdraw care.

I view these trends as antithetical to the origins of palliative care as means of providing comfort and relief, an evolving tradition dating back to the Irish Sisters of Charity who opened Our Lady's Hospice in Dublin in 1879. According to an account by Dame Cicely Saunders, the founder of the modern palliative care movement, the sole focus of the Sisters of Charity was the care of the dying.[19] Describing their hospice, it has been said that the Sisters of Charity observed, "It is not a hospital, for no one comes here expecting to be cured. Nor is it a home for incurables, as the patients do not look forward to spending years in the place. It is simply a 'hospice' where those who are received have very soon to die, and who know not where to lay their weary heads."[20]

That phrase, "weary heads," lingers with me since I read it over a decade ago, embodying the empathy, the compassionate care that so informed the palliative care movement as it marched through the 1990s fighting for legitimacy in clinical circles and fighting off those who more narrowly sought to use it to advance the case for physician-assisted suicide.[21] As advanced by its most thoughtful proponents, palliative care originated from a patient/family-centered stance that focused on relief of distress and closure, as well as an appreciation that patients and families came to decisions in their own way, in their own time. Each patient's trajectory would be unique, and the key to formulating a smooth glide path to a peaceful death was to help the patient to articulate goals of care. Decisions to withhold or withdraw care were never goals, in that framework. They were the means, meant to be derivative of a prior articulation of goals, desires, and aspirations, some of which could be satisfied in other ways.

In the intervening decade, much has changed. In too many cases, a clinician's angst about an impending death and sense of causality, or even responsibility, for a patient's demise has been replaced by the consolation that those who withhold or withdraw life-sustaining therapies are acting in a progressive fashion, invariably in the right, acceding to the patient's or the family's wishes. And, if that is wanting, then making decisions based on the superior judgment on such matters, that comes with medical practice. There is a certainty to these decisions replacing the ambiguity of clinical intentions and the moral angst that used to be felt. In short, this ideological belief in palliation and palliative care in a prescriptive way to die has taken some of the gravitas out of dying.

No longer just about securing a right to die, practices and beliefs have morphed so that a timely death has become proper and prescriptive. When patients don't die as expected, or on time, one hears house staff using the phrase "failure to die"—an echo on the earlier geriatrician's "failure to thrive"—to describe terminally ill patients who linger and refuse to die. A failure to die. . . . *We used to call that survival*. Now that is being seen as a failure, a strange twist since Wanzer wrote of death as a medical failure back in 1989.[22] That essay is also celebrating its jubilee, but so much has changed. From death as failure, to failure to die: Everyone is in such a hurry.

OF GOOD INTENTIONS

In cases both personal and professional, as a family member and a doctor, I have seen this rush to

judgment in which clinicians jump to a palliative care recommendation even before a diagnosis or prognosis was clear and before relationships were made with patient and family. These doctors were not disinterested nor motivated by malintent. They earnestly believed that what they were doing was right, and was what they had been trained to do in their courses in medical ethics and palliative care. They had good intentions, even as their presumed beneficence had unintended consequences.

A memorable case in point came to our ethics consultation service. A patient with endocarditis secondary to intravenous drug abuse was hospitalized in the intensive care unit, with a spinal cord abscess involving c3-c5. She had septic embolic to her head and lungs, compromising both her level of arousal and her respiration. Because of cervical cord compression at the roots of the phrenic nerves, the patient had lost ventilatory drive and was ventilated.

Because the patient was unconscious and in critical condition, her father consented to a DNR order. A few weeks later, the patient regained consciousness. Essentially locked-in because of her spinal cord lesion, she began to communicate with her eyes. Her doctors called for an ethics consult because she indicated she wanted to have her endotracheal tube removed and to die.

I was the consultant on call, and was asked by the patient's unit doctors to see her and validate this request so that they could honor her wishes and allow a dignified death.

When I met the patient, she was alert and clearly able to signal yes and no with her eyes. After some preliminary questions to ensure that she could follow instructions and answer consistently, and some additional neutral queries, I asked her if she wanted to die, as I had been told. She answered, No.

I confirmed that this was her answer and continued to ask about her endotracheal tube. "Do you want the tube out?"

Yes, she responded with her eyes.

"You would like the tube out?"

Yes, again with her eyes.

"You know that if I take the tube out you could die?"

Yes, she said looking straight at me.

"So you still want it out?"

Yes.

"So you want to die?"

No, she responded.

I repeated this sequence several times and in different ways, and came to the conclusion that she wanted the tube out, she understood that taking it out would cause her to die, and that she did not want to die. There was an inconsistency here, and I felt obliged to search for an explanation. After all, all the patient could do was to respond to my requests. She could not generate her own questions.

"So, let me summarize. You don't want to die, but you want the tube out? Correct?"

Yes.

And then, my hypothesis: "Does the tube hurt you?"

The question was met with a massive swooshing, downward gaze of her eyes, and even something of a grimace, which I translated as an emphatic *Yes.*

"So," I suggested, "You want the tube out because it hurts?"

Another expressive, *Yes.*

Adopting a palliative stance, I suggested that if she wanted to live, then we would need to keep the tube in until it was safe to take it out, or place a tracheostomy tube that would be more comfortable. That option was not possible because she was on a significant amount of pressure support, so the procedure could not be done safely.

So the patient and I agreed to a number of things, now that her goals were clear. First, we would rescind her DNR order, as she wanted to live. Second, she would be put under general anesthesia for a week, to seek if her lungs would heal, making tracheostomy placement possible. If that became an eventuality, we would waken her and obtain her consent for this. On the other hand, if her condition worsened and she would not be able to come off the tracheostomy tube, she directed us to reinstitute the DNR order and perform a terminal extubation.

She was placed under general anesthesia and continued to receive treatment for her systemic endocarditis, and emerged a week later as a candidate for tracheostomy placement. This was done, and she eventually went to rehabilitation.

A fortuitous outcome, but whatever had occurred, it is important to return to how the case was too easily framed as a right-to-die case, and how that changed. Over the course of 40 minutes of "discussion" with this patient, a "routine" withdrawal of care—presented by the patient's medical team with much self-satisfaction—had become something quite different. Through our conversation, we clarified that the patient never wanted a withdrawal of life support and did not desire death. Her request to have her tube removed, too easily interpreted as a euphemism like "pulling the plug," was actually a call for pain relief in a patient who had become voiceless due to her paralysis and intubation.

The desire to provide this patient a dignified death also suffered from a lack of credible eviden-

tiary information about the patient's prognosis. Her fate was presumed by the treating team to be far worse than her actual prognosis. After additional consultation, it was estimated that she had a 50 percent chance of independent respiration after the abscess was drained and treated with antibiotics. Why the "treating" team so quickly saw the patient's situation as terminal can only be surmised. We might speculate that it might have been related to prejudicial views towards her substance abuse and her "self-inflicted" illness, or due to cognitive bias, stemming from a framing effect engendered from an abscess overlying the critical roots of the phrenic nerve. Whatever the explanation, the forces of nihilism were working upon this case in a manner that distorted decision making to the point of almost sacrificing a patient's life.

SHALLOW BIOETHICS

When a preacher makes a point of criticizing a patriarch or the Deity, he or she is said to be "preaching against the text." It is an awkward place for a theologian, and equally so for a bioethicist. And so it seems that the case of the patient with metastatic cancer and the open sternal wound and the patient with the endocarditis are at odds with each other. In the first, I urge the doctors to clearly demarcate the limits of care. In the second, I critique the physicians who wanted to withdraw life-sustaining therapy. How are these two cases to be reconciled, with broader lessons drawn for clinical practice?

Although the first case urged less treatment and the second care urged more, it is the depth of the care, not the ultimate direction, that link these two cases together. Each case suffers from the same deficit, namely a failure to engage the patient and family more fully in dialogue and negotiation. They also suffer from a knowledge deficit that stems from such superficial engagement. In the first case, it was professionals ceding what they knew about the dangers of resuscitation. In the second, it was not knowing what was not known: neither the patient's true preference nor her prognosis.

Regrettably, these errors occurred under the guise of a *shallow bioethics*, true to neither principlism nor pragmatic approaches. It was sloppy, incomplete, and inattentive to both details of the cases and to the prevailing ethical principles that should govern practice. In the first, it was deference to autonomy at the expense of other ethical values and a corpus of medical knowledge that is the purview of clinicians. This embrace of autonomy, unrestrained by other principles or medical facts, was fundamentally a breach of professionalism, precluding more thoughtful responses about the risks of resuscitation.

In the second case, it was the enthusiastic endorsement of what seemed like an autonomous choice without subjecting that false belief to more scrutiny. It was an example of how an ideological embrace of what one believes is right can erode the contingency and skepticism necessary for safe clinical practice.

DISCOURSE IN TRANSLATION

When I began this essay, I suggested that the clinical ethicist was like the traveler who spoke an ancient language and was no longer understood, suggesting that he or she needed to brush up on modern Romance languages to gain entry to the conversation. But a close reading of the cases presented here suggest that I was wrong, and that it is the other way around. It was the intervention of a clinical ethicist that prevented iatrogenesis, either from a decision to attempt resuscitation when it was dangerous, or to forego it when in fact it was indicated and desired.

The trouble is that these errors were occurring under a *lingua franca* of clinical ethics. The *Oxford English Dictionary* defines *lingua franca* as "any mixed jargon used for intercourse between people speaking different languages."[23] And that is the case of clinical ethics in the clinic. The "professionals" in clinical ethics are coming from a background in the humanities and social sciences, as well as clinical practice. In contrast, their interlocutors have been acculturated in the language of science, which is more quantitative and reductionistic. They are indeed speaking different languages, placing them at a distance.

The result is that although there appears to be communication between practitioners and clinical ethicists, when we interact we actually each speak a second language in which neither of us are fluent. This lingua franca is a weak composite that neither captures the best of our ethical reasoning nor the excellence of sophisticated clinical decision making. This amalgam can lead to a shallow bioethics on the part of practitioners—and, as ominously—an equally thin notion of clinical practice amongst those clinical ethicists who are not otherwise trained in medicine or the health professions. This divide has been deepened by medicine's embrace of "evidence-based" practice, an approach that tolerates only certain kinds of evidence and dismisses that which is not falsifiable.[24] In this cognitive frame, numbers can easily become confused with values.

This is a dangerous mix. Each side, through the aegis of a shared lingua franca, sees a lack of depth in the discourse of the other, which can lead one unfamiliar with the richness of the other's "text" to be dismissive, and even disrespectful. These views are not the fault of what is actually there, but the shallowness of what is actually accessible through translation of a primary language's richness through a rickety vehicle like a lingua franca. So when we communicate in this shared language, neither side is at its best, each struggling to simplify and decrease complexity and nuance, to be understood across a linguistic—and here a conceptual—divide.

THE WAY FORWARD

While there may be deficits in our theories of bioethics—after all, nothing is without its flaws—I have come to appreciate that the challenge for clinical ethics *in practice* is more about how these theories are communicated, or rather miscommunicated and misrepresented, by those whose fluency is lacking both in the expression and reception of a complex text.

Our focus therefore should be less on theoretical disputations about the virtues of one method over the other. An analogy would be to ask who is the greater novelist, Hemingway or Woolf, when the audience can not speak English and no suitable translation is available. In that case, as in debating the merits of principlism versus pragmatism, the more pressing need is to build the language skills necessary for appreciating *any* method.

This will require enhanced—and more effective—training in clinical ethics, that integrates ethical reasoning early in the medical, nursing, and allied health curricula, so that students and trainees receive what amounts to a *bilingual* education. As they learn, for example, about the Krebs Cycle and the gluconeogenesis of starvation, they might also learn about the ethics of patients who voluntary decide to stop eating and drinking at life's end. This integrated approach will build the incremental fluency necessary to address complex problems in all their dimensions, and help the learner grasp both the significance of the science and the ethical significance of a patient's request.

Those who come to clinical ethics from earlier work in the arts, humanities, and social sciences will have a reciprocal need to become familiar with the clinical context within which they hope to contribute. This can be accomplished through masters or fellowship programs. Nothing short of a robust exposure and meaningful immersion in the clinical space—and the language of the clinic—will be adequate to equip these individuals with the "linguistic" skills to share their critical insights from nonscience domains with a clinical audience.

An early first step in bringing such standards to clinical ethics is an effort by the Quality Attestation Presidential Task Force of the American Society for Bioethics & Humanities (ASBH) that I have led as president of the ASBH, ably joined by Eric Kodish of the Cleveland Clinic.[25] This initiative has sought to begin a quality assurance process for those who would do clinical ethics consultation and to set minimal standards for the competency of those who practice this activity. We hope this model will have derivative educational benefits for healthcare professionals, as well as ethics consultants.

TOWARDS INTERDISCIPLINARITY

As daunting as the aforementioned challenges may appear, they are good problems to have. The need to replace our shared lingua franca of clinical ethics with something more substantial, a proper language more able to convey nuance and complexity and engender serious study, is a reflection of our collective evolution from a multidisciplinary field to a discipline that is truly becoming interdisciplinary. In the former case, people from multiple disciplines speak to each other in translation. In the later, multiple disciplines cross boundaries to coalesce using a common focus and a shared language. Seen in this light, the past 25 years have been extraordinarily formative, not only in the maturation of clinical ethics, but for its potential of transform the language of the clinical transaction itself.[26]

DEDICATION

This article is dedicated to the memory of John C. Fletcher.

MASKING OF THE CASES

The identities of the persons in the cases described in this article have been masked by changing nonclinical details of the cases.

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Features

Surrogates and Extra-Familial Interests

Ralph Baergen and William Woodhouse

ABSTRACT

A case is presented in which the therapeutic interests of the patient conflict with the safety of a community, and in which the surrogate decision maker has very limited knowledge of or concern for the patient's preferences. The substituted judgment and best interest (or rational patient) standards for surrogate decision making are problematic in this case. It is argued that the interests of even those outside the family ought to be taken seriously when making decisions about such cases, and it is proposed that clinical ethics committees could play a new role here. This case also illustrates the difficulties of making decisions regarding the treatment of a very unlikable patient.

INTRODUCTION

Surrogate decision makers are sometimes presented with situations in which the interests of the patient conflict with extra-familial interests (such as community interests). We do not currently have clear ethical frameworks or policy guidelines for addressing such cases, but this is an area in which hospital ethics committees may be well placed to assist in decision making.

CASE PRESENTATION

A neurosurgeon asked the ethics committee of a regional medical center to review the case of Mr. C. Details of the case have been altered to preserve the privacy of the patient and family. Mr. C is a late-middle-aged male, who, in his teenage years, had a brain tumor surgically removed and irradiated. Some years later he was incarcerated in a state correctional facility for sexually inappropriate behavior toward children. It is plausible that his sexual deviancy could be related to impaired inhibition from his brain tumor or its treatment.

After more than 20 years in prison, Mr. C was released in a physically debilitated and cognitively impaired state. He was incontinent, wheelchair bound, and functioning cognitively at or below a grade school level. His sister, the only family member officials could reach, agreed to look after his interests as best as she could; this included acting as the patient's surrogate decision maker for medical decisions. (She was so designated in Mr. C's durable power of attorney for healthcare form.) She reports sexually inappropriate advances toward her by the patient in the distant past.

When Mr. C was released from prison, he was admitted to a hospital near his sister's home and di-

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agnosed with a blockage of spinal fluid flow, for which a shunt was placed. His recovery was such that he could not be cared for in his sister's home. His sister was also concerned that the patient's sexual behavior could pose a risk to her two young children. Upon discharge, the only facility in the state that would accept a patient with his history of predatory sexual behavior was a private, secure, long-term psychiatric nursing facility in the far corner of the state.

Soon thereafter, Mr. C became seriously ill with life-threatening sepsis and meningitis related to infection of the shunt. He was admitted to a regional medical center where the shunt was removed and the meningitis treated with a prolonged course of antibiotics; he recovered well from his infection. Despite being critically ill, he was observed to masturbate compulsively in the emergency department and hospital.

Imaging tests revealed evidence of the prior brain tumor surgery and a large tumor mass in his neck that was pressing on his spinal cord. The neck tumor was determined to be the likely cause of his worsening lower extremity weakness and incontinence. A psychiatrist evaluated the patient and found that he was not competent to make his own healthcare decisions.

The neurosurgeon determined that the tumor in Mr. C's neck would probably continue to grow slowly, cause progressive disability, and could shorten the patient's life. It was also his opinion that removal of the tumor, although associated with some surgical risk, would arrest the deterioration in Mr. C's physical function and probably improve his level of function. Tumor removal would probably allow for a lower level of care and a higher level of independence. Although clinical outcomes vary considerably in such cases, there is a good chance that this treatment would improve Mr. C's competence and ability to ambulate, increasing his opportunities to interact with others (inside and outside the facility); thus, treatment holds out the possibility of a marked improvement in the patient's quality of life. Surgery would not affect his cognitive functioning or his lack of impulse control, so this patient would require a higher level of supervision and could place other residents and the community at greater risk.

The neurosurgeon worried that improving Mr. C's mobility and functioning may lead to his no longer satisfying criteria for continued care at the secure psychiatric nursing facility. If he were to be released to a less restrictive facility, or onto the street, he would be less likely to receive appropriate care and might engage in his prior pattern of sexually predatory behavior. His sister did not want him returning to her home because of her concerns for the safety of her own children. The ethics committee pondered whether the interests of the community (keeping a potential sexual predator off the streets) should play any role in their deliberations.

SUBSTITUTED JUDGMENT OR BEST INTEREST?

The surrogate in this case is the patient's sister, but she has had little or no contact with the patient since they were young adults. When they were in their teens, the surrogate was a target of the patient's inappropriate sexual behavior (although it was not reported at the time or punished). There are no other family members or close friends who could act as this patient's surrogate, and the sister's decisions are closely monitored by the attending physician (in consultation with the ethics committee) to ensure that she appropriately fulfills her responsibilities.

Although this patient has been autonomous (to some degree) in the past, the substituted judgment standard is not appropriate as a guide for surrogate decision making in this case.[1] The patient's period of autonomy was relatively brief and declined rather sharply (probably in his late teens) when his brain tumor was found and treated. The surrogate does not recall the patient's views from that period in any detail (and, in any case, who among us would want our medical decisions guided by views we held in our teens?). Therefore, the surrogate should probably be guided by the best interest standard (also known as the reasonable person standard).

The Best Interest Standard and Its Problems

The best interest standard has long been recognized as being problematic.[2] Many of these difficulties arise from the vagueness inherent in the concept of an incompetent patient's best interests; these will not be explored here.[3] But difficulties also arise when the patient's interests conflict with those of family members (or others).

The Patient's Interests

Let us assume that patients generally want to have their preferences fulfilled in the absence of higher level preferences to the contrary (for example, a smoker who wants a cigarette, but who also wants to stop smoking). In this case, Mr. C might well want to be able to gratify his desires, and he seems to lack the cognitive capacity to reflect critically upon them. Thus, one might argue that the surrogate should

make treatment decisions to maximize the satisfaction of his desires. This would involve consenting to surgery and associated treatment for the tumor in his neck, probably resulting in a higher level of physical functioning. Unfortunately, this patient's most noticeable desires are sexual in nature and have previously led him to harm others. So, treatment decisions based on a simple desire-gratification view of interests would maximize the likelihood that he would return to his predatory ways. This simple preference fulfillment approach indicates that the patient's interests and those of the community would be in conflict.

DeGrazia has argued that not all desires are equal when it comes to determining one's interests; he says we should consider only the gratification of "informed" or "rational" desires.[4] If a desire is "informed" only if the patient himself or herself is in possession of the relevant information and grasps its significance, or "rational" only if the patient has her- or himself arrived at it via reasoning (or could so reason, if prompted), then this patient's low cognitive functioning may prevent him from having any qualifying interests. But surely patients with very limited cognition still have interests, so perhaps we should be guided instead by those desires that would be held by a hypothetical informed and rational agent. It seems likely that this set of desires would include wanting to maintain health and a high level of functioning, experience satisfaction, and avoid pain, discomfort, indignity, and so forth.

Although these desires are very different from this patient's primitive sexual urges, treatment decisions guided by them will be much the same. As before, the surrogate would select treatment to remove the tumor in the patient's neck and restore physical function (but without improving cognition, changing the patient's urges, or giving him the capacity to govern his behavior). Given the problems with finding a suitable treatment facility or program, it seems likely that this patient would eventually be released into the community, where he would pose a hazard to others. Those involved in the ethics consultation were not aware of any other treatment alternative that would both address his declining function and yet maintain his eligibility for residency in the secure facility. So, the "rational desires" approach also involves a conflict between the patient's interests and those of the community.

Incorporating Family Interests

When decision-making guidelines such as the substituted judgment and best interest standards were first developed, surrogates were instructed to focus on the patient, giving very little weight to the interests of others. The President's Commission argued that surrogates should take the family's interests into account only if the patient would have done so.[5] Similarly, some commentators asserted that "the family's rights *vis à vis* the medical care of an adult are limited to ensuring that the wishes of the patient are fulfilled and to expressing their considered judgment regarding what is in the best interest of the patient, given their presumably more intimate knowledge of the patient and his life and values."[6]

It wasn't long, however, before ethicists challenged this narrow focus, arguing it was permissible and appropriate—perhaps even obligatory—for surrogates' decisions to be influenced by the family's interests. Hardwig, for instance, held that the interests of family members are legitimate and should be taken into account regardless of whether the patient (if competent) would have done so.[7]

Family relationships play several roles here. First, they make it likely that the patient's family members will have adequate knowledge of the incompetent patient to make judgments about which goals should be pursued, which risks are worth taking, and so forth.[8] Second, these relationships provide a sort of authority to make these decisions.[9] Third, and most importantly in this context, when the interests of the family or its members conflict with those of the patient, the family has a special claim to have those interests taken seriously. In some cases, the family may permissibly decide upon a treatment that is less than optimal for the patient in order that the interests of family members are not unduly thwarted. (It is worth noting that family relationships also make these tasks much more difficult in some ways. Surrogates are called upon to make complex decisions in the face of medical uncertainty, grief, financial stress, financial conflicts of interest, relational ambiguity, and so forth.)

There are, however, important boundaries to be observed when surrogates make these decisions. Kopelman argues that surrogates' decisions "must meet at least a minimum threshold of acceptable care,"[10] and Kapp explains that treatment decisions must "serve a therapeutic interest of the patient."[11] The interests of family members may be taken into account, but not to the extent that the well-being of the patient is entirely overridden.

Extra-Familial Interests

In addressing these patient-family conflicts, the literature on surrogate decision making has tended to assume that family interests may be taken into account because they are *family* interests.[12] If the

treatment that is optimal for the patient would involve serious burdens for the family, this line of reasoning leads to the conclusion that families (acting as surrogates) are permitted to choose some suboptimal treatment, provided it meets certain minimum standards.[13] But it is still assumed that if the patient's interests conflict with those of someone outside the family, the surrogate's role is to give them no consideration. For instance, if the patient would benefit from something that is in short supply (for example, a transplantable organ or a bed in a treatment program), family members acting as surrogates are permitted (and expected) to select them, despite the fact that doing so may conflict with the interests of the strangers competing for those resources. Similarly, Mr. C's sister would be permitted to choose a suboptimal treatment site if doing so would protect her children against this patient's behavior, but she would not be permitted to make that choice if her sole reason were to protect strangers.

It does not follow, however, that the interests of those outside the family should receive no consideration. The *surrogate* may not consider the interests of strangers when making treatment decisions, but this does not mean that those competing interests have no moral weight. Viewed from an ethical perspective, there is no sharp boundary between family members and others. Instead, we find ourselves in networks of relationships with family members, friends, neighbors, colleagues, community members, and so on. When a case can be made for incorporating the family's interests in a medical decision for an incompetent patient, a broadly parallel argument can generally be constructed for the conclusion that extra-familial interests ought to be considered as well.

For instance, consider Hardwig's discussion of surrogates and family interests:

> Because medical treatment decisions often deeply affect more lives than one, proxy decision makers must consider the ramifications of treatment decisions on all those who will be importantly affected, including themselves. Everyone with important interests at stake has a morally legitimate claim to consideration; no one's interests can be ignored or left out of consideration. And this means nothing less than that the morally best treatment in many cases will not be the treatment that is best for the patient.[14]

Nothing in this argument relies on the nature of families. If justice requires that the family's interests be considered when making decisions for patients, then a parallel line of reasoning leads to the conclusion that the interests of non-family members and broader social interests ought to be considered, too.[15]

The conflict about whether the interests of others should be taken into account when making the patient's treatment decisions may be rooted in a disagreement about which moral perspective to adopt. Consequentialism would support incorporating the interests of strangers in these treatment decisions, whereas a focus on respect for autonomy and the right to self-determination would tend to allow the (limited) consideration only of family interests (because of the role of the family in the formation and function of the individual).[16] The consequentialist perspective conflicts with the patient-centered approach to practicing medicine, although it fits well with the population-focused approach to public health, and with distributive justice.

There are already familiar and established mechanisms for balancing the interests of patients against those of strangers. When allocating transplantable organs, for instance, we routinely balance patients' interests against one another—a process in which consequentialist ethical principles are far more prominent than autonomy or self-determination.[17] When a surrogate's choice of a transplant is a poor use of those resources, that decision is rightly overridden.[18]

Consider the public health response to outbreaks of infectious disease when the disease is serious, easily spread, and we lack vaccines or other effective prophylaxis. In such circumstances, quarantine and other measures are commonly taken, even though they are designed to benefit others at the expense of those who have been exposed.[19] Exposed individuals who want to move about freely would have that decision overridden; their individual interests would conflict with and be overridden by the community's interests. As with allocation decisions, public health utilizes consequentialist reasoning to balance competing interests in ways that have found broad support. There is no reason this model cannot be adapted for balancing patients' interests against those of people outside their families.

This has already found its way into the literature on surrogate decision making. For instance, these extra-familial interests are noted explicitly by Brody:

> While the interests of the patient will often be the predominant factor to consider, in part because of obligations of promise keeping and fidelity to the patient and in part because the patient is the most affected, there will be cases in which the interests of others (family members, caregivers, society) take precedence, because

> these are cases either in which the interests of others are affected far more than the interests of the patient or in which the caregivers have greater obligations to others.[20]

Kopelman agrees that legitimate interests should be taken into account regardless of whether these arise within the patient's immediate family: "The best interests standard was introduced to give incompetent patients legally enforceable rights to a minimal level of care," but this "does *not* require ignoring all other duties, allocation plans for scarce resources, or others' interests in deciding what ought to be done for someone."[21] There are legitimate worries, however, about having the *surrogate* try to balance the patient's and family's interests as well as extra-familial ones.

Who Should Balance Competing Interests?

If extra-familial interests are to be taken into account, who should do it and how? When the patient is incompetent, the surrogate has authority to make choices and consent to treatment, but she or he ought not to be responsible for weighing all the competing interests when they include (as in this case) factors beyond the family. The surrogate's role is chiefly to promote the patient's interests and secondarily to balance those against conflicting *family* interests. But when broader social concerns arise, the task of balancing these factors—and thus the final decision about what to do—should lie elsewhere. Brody both acknowledges the legitimacy of extra-familial interests and warns against having the surrogate try to resolve conflicts among these and the patient's interests: "The role of the proxy decision maker is to speak in place of the patient, to advocate what the patient would have advocated. That is the point of the substituted-judgment standard. It remains for others to decide whether to accept that advocacy. They usually will, for all the familiar reasons. But when the interests of others are more affected, or when other special obligations are present, they will not."[22]

Unfortunately, there does not seem to be any body charged with this responsibility, any clear ethical guidelines, or any supporting policy or legislation for this sort of decision making. Public health agencies, policy, and legislation provide this structure for balancing competing interests during an outbreak of infectious disease.[23] For allocating such resources as transplantable organs, we have the federal government's contract with the United Network for Organ Sharing, with its scoring systems, waiting lists, and so forth. But for other kinds of circumstances, we do not yet have any mechanism or guidelines for balancing the interests of a patient against those of individual strangers or entire communities.

Public health and resource allocation systems provide a consequentialist framework balanced with the recognition of individuals' rights that would be suitable for this weighing of competing interests. In a case such as this, it seems likely that the interests of the community that are at stake would *not* override the patient's therapeutic interests; that is, a system for balancing the interests of the patient and the community would reach the conclusion that the surrogate's decision to proceed with surgery (to remove the tumor from the patient's neck) should be honored. After surgery, Mr. C may no longer be eligible for treatment in a secure facility, and he may once again pose a risk to others. But there is no certainty that others would be harmed, and the risks involved can probably be mitigated by means less drastic than withholding treatment (although those have yet to be determined). If there were greater certainty that the patient's release would result in harm to others, and if there were no less drastic means of avoiding that harm, then we could build a compelling ethical case that the surrogate's decision to proceed with surgery should be overridden.

The hospital ethics committee that considered the case presented above discussed the interests of the community, but did not want to undertake the responsibility for balancing those against the patient's interests. Even so, this may be where the balancing ought to take place. In the committee's deliberations, the physician could present the patient's "therapeutic interests"; the surrogate (if a close friend or family member) could provide more information about the patient's interests and balance those with other family interests; and one or more other committee members could present the case for extra-familial interests (for example, the health and safety of the public). (The ethics committee might play this role even if the case did not involve an incompetent patient represented by a surrogate decision maker.) This would be faster, less expensive, and less confrontational than trying to resolve these issues through the courts—provided these committees are provided with the appropriate legal and policy framework.

This process would be complicated in cases such as this by the fact that the patient is very unlikable. It is very tempting to withhold treatment to punish the patient for his past behavior or his perceived moral character, to overestimate the probability that he will cause harm, and so forth. The ethics committee worked hard to avoid these pitfalls, and tried

to focus on Mr. C's medical needs and on bringing about the best outcome from his perspective; the issue of protecting the community was left to (unspecified) others. In such cases, the surrogate or ethics committee should push aside any distaste or dislike for the patient, and focus on what is medically indicated and what would improve the patient's quality of life (as the patient sees it).

If hospital ethics committees are to be given the role of balancing the patient's interests against those of the community, important practical challenges will have to be overcome. This role is not among those traditionally assigned to hospital (or other) ethics committees.[24] It will be difficult to design a system that insulates the committee's deliberations from inappropriate influences such as the personalities of its members, the likability of the patient, the interests of the institution, and so forth. Nevertheless, this task should be undertaken; the alternative is to continue to neglect morally weighty considerations.

CONCLUSION

This case illustrates that when the interests of the patient conflict with those of the community, some means of balancing these interests is ethically required, but no practical structure currently exists to handle it. The functions of hospital ethics committees could be extended to address this need.

Cases such as this would probably become more common if political or economic factors lead to reductions in healthcare facilities and programs. We need to prepare our institutions and communities by developing the appropriate laws, policies, and the ethical analysis on which they should be founded.

NOTES

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Familiar Interests and Strange Analogies: Baergen and Woodhouse on Extra-Familial Interests

James Lindemann Nelson

ABSTRACT

The article by Professor Baergen and Dr. Woodhouse makes a succinct and serious contribution to progress in bioethical understanding of deciding for others.[1] They begin with what is by now a familiar claim: family proxy decision makers may sometimes make decisions on behalf of incapacitated relatives that depart from what might be optimal from the patient's point of view, since the well-being of family members, or of the family as such, may be substantially affected by the direction of a patient's care. They then develop this idea, noting that others apart from family members can also be substantially affected by a patient's treatment, and arguing that the interests of strangers ought also to sometimes have a role in determining the aims and means of a patient's treatment.

Baergen and Woodhouse also devote attention to how extra-familial interests might be implemented in medical decision making. While I unearth a troubling consequence of the effort to realize their theoretical conclusion practically, my chief task is to point to some disanalogies between families and strangers, and consider the extent to which they call into question the relevance of the interests of strangers to the treatment of patients.

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Since John Hardwig's path-breaking article in 1990 in the *Hastings Center Report*, "What About the Family?"[2] there has been persistent attention to his thesis that, at least in some circumstances, burdens encountered by families resulting from medical treatment of relatives can be substantial enough to justify allowing family interests to count on their own behalf in deliberations about appropriate care; Baergen and Woodhouse's article continues that tradition. It is, perhaps, at least mildly ironic that nearly a quarter century ago, Hardwig motivated his view by pointing to the ways in which extra-family interests were already being used to trump conflicting patient interests. As non-patient interests that affect the wider society were increasingly regarded as morally relevant to deliberations concerning patient care, Hardwig asked how we could justifiably ignore family interests, which can be so much more immediate and individually burdensome.

Baergen and Woodhouse stand Hardwig's strategy on its head, arguing that as family interests are in principle legitimate contributors to decisions about appropriate care, so must be the interests of

strangers. Relatives may indeed suffer from certain treatment decisions made to further a patient's best medical interests, but what is pertinent is not that they are *family* but that they are *vulnerable;* hence, medical decision making needs to be alert to the impact on everyone affected by it.

They develop this point with some delicacy. In the discussion of their arresting case study, they do not insist that extra-familial interests trump the interests of Mr. C. For example, they cite, with apparent approval, arguments concluding that patients' special place in decisions affecting them imposes limits on the degree to which their interests can be set aside by contrary family needs or desires—although just where such limits lie in extra-familial contexts is left as an exercise for the reader. However, the circumstances facing Mr. C suggest that the authors regard the scope and stringency of any special protection that patient interests enjoy to be negotiable, as extra-familial interests in Mr. C's case are presented as appropriately bearing on whether he should be denied surgery that might arrest a progressive disabling condition, substantially increase his mobility, and even extend his life.

Baergen and Woodhouse explicitly acknowledge that the harms to others posed by Mr. C's treatment remain speculative. They also allow that withholding surgery may not be the only practical safeguard against the danger he presents.[3] What makes their view so striking, however, is not so much decisions as deliberation: the fact that Mr. C's treatment, given his circumstances, might make other people much worse-off, cannot be excluded as impertinent to what treatment will be offered him.

One reasonably plausible and readily available way of responding to this bold view might be by claiming that the relationship between healthcare providers and their patients remains defensibly "paternalist," although not in the "doctor knows best" sense. Rather, like parents, health professionals do not aim at what is best for humanity over all, but what is best for those to whom they are in a morally special relationship. In effect, Baergen and Woodhouse's response to this objection can be seen in their employment of consequentialism, a topic I'll turn to below. What seems more on their mind is the vexing question of how to identify a mechanism to determine when extra-patient interests are under grave enough threat to shift treatment decisions away from those that the patient favored, or that would have best promoted her own interests.

For Baergen and Woodhouse, a big challenge is guarding against the fact that Mr. C is decidedly unlikable, both because of its bearing on the instant case, and because they seem to think that many patients whose relationship to other people will put in question whether they should receive treatment that best serves their own interests are prone to be similarly unlikable.

My primary implementation concern is different. Suppose Mr. C were not a decisionally incapacitated, mobility-impaired sex offender. Suppose he were instead a politician in high office bent on manipulating intelligence data to foment a needless war. As it happens, Mr. C requires, say, a heart transplant, or a new pacemaker. (He might still be singularly unlikable, but that seems of less moment in this version of the case.) Would it be possible for healthcare professionals, or an ethics committee for that matter, to deliberate whether the threat such a man posed to tens or hundreds of thousands of people, and possibly to the entire world, made it legitimate to withhold the needed surgery?

The notion of denying healthcare to a Strangelovian version of Mr. C might strike some as a *reductio* of the Baergen-Woodhouse view, but that's not how I intend it. The point, rather, is to raise the worry that among the challenges their view faces is how to administer it in ways that will not be significantly biased against the relatively poor and powerless. That our authors are concerned that the conflicts between patient and extra-familial interests are likely to grow "if political or economic factors lead to reductions in healthcare facilities and programs" suggests that their paradigm for the socially problematic patient is someone much more like their Mr. C than like my highly placed political version.[4] If the extent to which a patient's interests are taken as central in determining treatment is influenced by his social and economic standing—and it seems highly plausible that the threats posed by the poor would be much more under discussion than those posed by the wealthy—whatever mechanisms determine the impact of extra-familial interest would have to be carefully tailored to avoid rampant unfairness.

If the concern about the justice of implementing decision-making policies and practices that are sensitive to extra-family interests raises serious issues for Baergen and Woodhouse, why should not they also trouble Hardwig and those influenced by his thinking? After all, their Mr. C is, in part, facing this problem because neither his society nor his family seems willing to make secure provisions for his subsequent health and social care. If Mr. C had extensive private means, he would not need his sister to provide him with the situation he needs. Once again, it seems, it is patient- centeredness for the

rich and powerful, trade-offs with families and strangers for those without money or might.

Is there, then, any ground for thinking that the interests of family members have a special importance that extra-familial interests lack? Baergen and Woodhouse themselves suggest one interesting candidate. They hold that the relevance of extra-familial interests is revealed by consequentialist moral reasoning, "whereas a focus on respect for autonomy and the right to self-determination would tend to allow a (limited) consideration only of family (because of the role of family in the function and formation of the individual)."[5] This pregnant parenthetical phrase deserves greater attention than they give it. Just what is it about "the role of the family in the function and formation of the individual" that makes family needs and desires—even if they run counter to a patient's medical interests—relevant to the exercise of the patient's autonomy or right to self-determination? If these considerations turn out to be at all robust, they would seem to spell trouble for their argument, which is that the motivation for taking family interests into account has to do with how treatment decisions effect others *as such,* without regard for any more complicated ways in which those interests might or might not relate to those of the patient.[6]

Rather than pursue this line of thought, their strategy is to maintain that consequentialist moral approaches—by which I take them to mean impartialist, "each counting for one, no one for more than one," utilitarian-style consequentialism—support the extra-familial interests claim, and that such an impartialist perspective is appropriate to clinical decision making. If so, this would undermine the objection that the professional-patient relationship, like the parent-child relationship, is morally special, and hence deflects the claims of the overall good impartially considered. In defense of the appropriateness of consequentialism to clinical decision making, Baergen and Woodhouse remind us of its predominate role in decision making around the allocation of organs, or in public health. If we can defensibly base decisions on consequences there, the suggestion seems to be, there are no in-principle barriers against doing so in other healthcare contexts.

Once impartially considered consequences are acknowledged as belonging squarely in the decision-making picture, the relevance of both familial and extra-familial interests seems natural. This is so even if we think of the claim of extra-familial interests as based in distributive justice, *à la* Hardwig's initial defense of familial interests, since, as Baergen and Woodhouse see it, distributive justice is a moral notion more closely allied to consequentialism than to respect for autonomy and self-determination, which seem to be the going alternatives.

Yet the situation here is less straightforward than they suggest. Portraying public health ethics as a paradigm for the ethics of clinical encounters is at least a conspicuous enough position to need some argument. Further, the way in which Baergen and Woodhouse deploy the organ procurement analogy seems a bit tendentious. For one thing, when there is simply not enough of a resource to go around, making decisions on grounds other than patient need or desires seems inescapable. Further, the criteria used to assign transplant candidates' places on waiting lists are construed typically as emerging from efforts to balance consequential and deontic concerns, to promote optimal efficiency *within* the constraints of equity. This explains why urgency of need—how soon one is likely to die for the want of a transplant—is such a significant factor in the allocation of vital organs. Impartialist consequentialism would presumably direct decision makers to put a premium on how likely a candidate was to live a long and healthy life with a transplant, rather than how likely she was to die soon without one. The treatment of Mr. C's case is, in fact, reminiscent of earlier and now unpopular efforts to allocate life-sustaining therapies via notions of the "social worth" of the recipient. If, as George Annas memorably quoted in a reference to the days of the "God Committee" that determined access to early dialysis in Seattle, "the Pacific Northwest was no place for a Henry David Thoreau with bad kidneys," a renally impaired, decisionally incapacitated pederast would likely have an even worse lookout.[7]

Of course, Baergen and Woodhouse might not be at all disconcerted by such an implication. Taking social worth into account—at least in some dimensions of that commodious notion—is just what they advocate, and expanding the remit of ethics committees (although not perhaps to a Divine pitch), just what they call for. Further, they might point out, even if considerations other than maximizing good consequences are at work in organ allocation as currently practiced, it is not at all clear that they have anything to do with any "special" moral relationship between providers and recipients of healthcare, nor even that those considerations involve respect for patient autonomy or self-determination.

If respect for autonomy is a matter of patients getting what they want, this is so. Yet considerations of justice in distribution are quite typically understood to reflect an appreciation of the special moral status of persons that also is expressed in terms of

respect for their autonomy. Morality, commonly understood, frowns on treating others solely as means to ends that they have not themselves elected, even if those ends would maximize the overall utility; presumably, that has something to do with honoring our status as beings that can choose for ourselves what we value.

Further, it is just this sort of nonconsequential conception of distributive justice that may help us understand how family interests might be relevant to medical decision making in ways that extra-familial interests are not—how they might count, that is, even if there is something morally privileged about a patient's relationship to his professional caregivers. Let's return to the point of distinction between families and strangers that Baergen and Woodhouse themselves note—"the role of family in the function and formation of the individual"—and try to sort out its connection to respect for autonomy. Families are characteristically the crucibles of our autonomy, providing both the "self" of self-determination and the stuff of which many of our values are made, either directly (we "inherit" them) or in reaction (we individuate ourselves by developing some values and ways of valuing that stand out against those prevalent in our families). Because of their proximity to the development or exercise of a patient's values, close family members are often taken to be generally in the best position to know or accurately reconstruct what decisions an incapacitated patient would make. How true this is (and how true it needs to be) is actively disputed.[8] But the presumptive appropriateness of families as proxies may not be solely a matter of their ability to accurately reproduce (or reconstruct) the decisions a patient would have made on her own. Surely, in at least some cases, incapacitated patients will have no determinate preference about treatment at which the family can aim, accurately or not; in other cases, the very reaction of the family to the kind of situation in which the patient finds herself would be among the circumstances that a patient would have taken into account had she been able to do so.

But if those most closely bonded to us cannot always convey the content of our choices, they may still choose in ways that reflect who we are more closely than others could. To issue in decisions, the various things that matter to us have to assume a certain pattern of salience, in light of our understanding of particular sets of presenting circumstances, possibilities of response, and the odds of various outcomes. It is their relation to *that* dimension of decision making—a dimension pertaining more to the distinctive ways we exercise our agency than to the specific choices we make—that family members may share with their familial intimates. The sense that we may share not just *what* we value, but *how* we value, may make intelligible the fact that some people seem as interested in who makes decisions for them as in what is decided.

These considerations do not at all imply that various family members cannot have sharply opposed interests. They are, however, meant to indicate how the role of families in the function and formation of individuals may make deliberation leading to decisions that differ from those a patient might have made for himself, yet emerge from a process that the patient would recognize as "familiar"—and therefore as less heteronomous than the decisionally effective interests of strangers.[9]

There are other potentially distinguishing points that could be explored. If notions of "shared agency" seem a reach too far, family members may sometimes have a certain sympathy for each other's values, needs, and desires, even if their own are different; if my interests as a patient have to lose out, it may still make a difference to me to whom I lose. Further, a patient's best medical interests are sometimes achievable only by decisions that in effect draft family members into prolonged, exacting service; while at least in principle they could simply "opt out," it seems very plausible to think that everyone's interest might be better served by trying to craft compromises that take seriously not only a patient's medical interests, but also preserve connections among family members without exploitation. And so forth.

Even if, however, these or related considerations do constitute disanalogies between families and strangers relevant to proxy decision making, they do not show that extra-familial interests are irrelevant to medical decisions outside of scarcity or public health threats; rather, they contribute to appreciating part of what needs to be done before that provocative view can be assessed with any determinateness. Baergen and Woodhouse have left bioethicists with another intricate and important complication to consider in understanding how to decide for others—for which they ought to be thanked.

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NOTES

1. R. Baergen and W. Woodhouse, "Surrogates and Extra-Familial Interests," in this issue of *The Journal of Clinical Ethics.*

2. J. Hardwig, "What About the Family?" *Hastings Center Report* 20, no. 2 (1990): 5-10.

3. Berger and Woodhouse, see note 1 above.

4. Ibid.

5. Ibid.

6. Hilde Lindemann and I have explored this idea in some detail, both jointly and severally, in a variety of places. See, for instance, chapter two of H.L. Nelson and J.L. Nelson, *The Patient in the Family* (New York: Routledge, 1995), and, more recently, J.L. Nelson, "Trusting Families: Responding to Mary Ann Meeker, 'Responsive Care Management: Family Decision Makers in Advanced Cancer,' " *The Journal of Clinical Ethics* 22, no. 2 (Summer 2011): 123-7.

7. G. Annas, "The Prostitute, the Playboy, and the Poet: Rationing Schemes for Organ Transplantation," *American Journal of Public Health* 75, no. 2 (1985): 187-9.

8. On these disputes, see D.I. Shalowitz et al., "The Accuracy of Surrogate Decisionmakers—A Systematic Review," *Archives of Internal Medicine* 166, no. 5 (2006): 493-7, and the classic paper by A. Seghel et al., "How Strictly Do Dialysis Patients Want their Advance Directives Followed?" *Journal of the American Medical Association* 267 (1992): 59-63.

9. H. Lindemann and J.L. Nelson, "The Surrogate's Authority," *Journal of Medicine and Philosophy* (forthcoming, 2014).

Challenges to Culturally Sensitive Care for Elderly Chinese Patients: A First-Generation Chinese-American Perspective

Karen C. Chan

ABSTRACT

Physicians and medical institutions in the United States are placing increasing emphasis on providing culturally sensitive care for patients, such as implementing a Confucian family-based model of medical decision making when caring for elderly Chinese patients. In this article, I articulate various reasons why deferring to the family is not a guarantee of culturally sensitive care, particularly when family members are first-generation Chinese-Americans. Nonetheless, I offer several suggestions to help physicians, medical institutions, and family members to provide more culturally sensitive care for elderly Chinese patients.

Within the United States, medical institutions and physicians are placing increasing emphasis on providing medical care that is sensitive to the cultural beliefs and needs of patients, with the goal of improving "access to care, quality of care, and, ultimately, health outcomes."[1] The U.S. Department of Health and Human Services Office of Minority Health, for example, published in 2001 its "National Standards for Culturally and Linguistically Appropriate Services in Health Care."[2] In this document, the DHHS recognizes the importance of providing culturally sensitive healthcare and sets national standards for healthcare organizations to encourage cultural sensitivity.

When it comes to treating Chinese patients in the U.S., and particularly elderly Chinese who have immigrated to the U.S., most institutions and physicians are prepared to implement a family-based approach to medical decision making, due to the recent attention in the literature concerning Confucian medical ethics. The assumption seems to be that by adopting a family-centered model for medical decision making for Chinese patients, not only are medical practitioners in the U.S. being culturally sensitive, but family members will be able to further guide physicians in providing culturally appropriate care for the patient. There seems to be a certain reliance on family members on the part of physicians and medical institutions in the U.S. to lead the way toward providing culturally sensitive medical care.

However, in this article I argue that deferring to the family is not a guarantee that culturally sensitive medical care, that is consistent with a patient's Chinese beliefs and values, will be delivered to the patient, particularly when family members are first-generation Chinese-Americans (or members of subsequent generations) who are not well versed in Chinese customs and traditions. Family members may be unsure of how to provide culturally sensitive care, and thereby be hesitant to take on full decision-making responsibilities. I further argue that

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despite the possible ignorance of Chinese customs, the family (even first-generation Chinese-Americans) should still be the locus of decision making for elderly Chinese patients in the U.S.[3] Nonetheless, I offer several suggestions to help physicians, medical institutions, and family members to provide more culturally sensitive care for elderly Chinese patients.

CONFUCIAN MEDICAL ETHICS—A FAMILISTIC MODEL OF MEDICAL DECISION MAKING

Medical ethics is a rather young discipline in the West, having only emerged as an area of academic focus in the 1970s. Western approaches to medical ethics tend to focus on such topics as patients' autonomy, the doctor-patient relationship, truth-telling, and so on. In the past few decades, however, an increasing amount of attention has been paid to articulating Chinese approaches to medical ethics, as found particularly in Hong Kong and China. Whereas Western medical ethics focuses on the individual patient, the Chinese approach, heavily influenced by Confucianism, employs a family-care model. For Confucians, the family is the basic unit of society; more than a mere collection of individuals who are related by blood, the family is a metaphysical reality "that reflects the deep structure of the universe and carries a profound sense of necessity and normativity for human life."[4] Thus, the Chinese patient is not seen primarily as an individual, but as a member of a family. The family unit makes decisions regarding the medical care of any particular member; the family, rather than the individual, is best able to look out for the interests of the patient as a member of the familial whole. The virtue of filial piety is of central importance; for an individual person to fully realize humaneness and to relate properly to others in society, he or she must pay proper respect to parents and familial elders. Out of proper respect and filial love, it is the duty of the family to care for other family members (and particularly the elderly), which includes making decisions about medical care.

Note how different Chinese medical ethics, with the family as the center of the decision-making process, is from medical ethics in the West. The values of autonomy and self-determination of the individual patient in the West are replaced by emphasis on the patient as a member of a family in the East. It is not for the Chinese patient to determine his or her own course of medical care independently of family, but, rather, family members participate in the decision-making process.[5] As a result, the Western value of patient confidentiality is foreign in the East, where doctors oftentimes do not hesitate to speak about a patient's medical status or diagnosis with the family before speaking to the patient. The family is of such importance in Chinese culture that, if the family deems that a patient should be protected from bad news about his or her medical condition, the physician should honor the wishes of the family. After all, it is assumed that the familial whole knows what is best for the individual family member, and that the family is best suited to look after the good of both the family as a whole and of each family member. According to this Chinese approach, physicians are allowed to lie to a patient about his or her medical condition if the family so requests:

> If a fatal diagnosis or prognosis is involved, most physicians in the East would be willing to follow the family's preferences to withhold the truth from patients, regardless of the patients' preferences. Moreover, they don't think it is immoral to lie to patients in such cases. A general difference between the Western physician and the Eastern physician regarding such cases is clear: the Western physician would need a strong argument to justify deceiving the patient, while the Eastern physician would need a strong argument to justify telling the truth to [the] patient."[6]

Scenarios in which it would be permissible—or even advantageous—for a physician to lie to the patient, however, simply do not exist (with the exception of extreme cases such as lying in order to prevent a patient from committing suicide) in the West. Ethical codes in the West forbid a physician from lying to a patient, irrespective of the family's requests.

CULTURAL BELIEFS AND ATTITUDES RELEVANT TO MEDICAL CARE

With the recent emphasis on providing culturally sensitive care to patients, more and more physicians and medical institutions are familiar with the role of the family in providing care for elderly Chinese patients in the U.S. By including the family in the decision-making process, physicians and medical professionals are not only demonstrating sensitivity to the Chinese patient's cultural values, but also hope that the family can guide the physician in how to further provide culturally sensitive medical care that is in line with the patient's cultural beliefs and attitudes. One of the reasons for this reliance on the family in providing culturally

appropriate care is that the majority of physicians and medical institutions are unfamiliar with the complexities of Chinese attitudes toward medical care, sickness, health, death, and dying. There has been no systematic study chronicling Chinese cultural beliefs and attitudes relevant to medical care in the West, so there is no concise reference guide for physicians and institutions. Although some hospitals provide guidelines for providing medical care to Chinese patients that mention some predominant cultural beliefs and attitudes concerning pain, the role of the physician, et cetera, these guidelines barely scratch the surface of the complex beliefs and attitudes that are common to the Chinese, and particularly older generations of Chinese.[7]

In this section, I attempt to summarize a few of the common Chinese beliefs/attitudes/superstitions/taboos that may be relevant to caring for elderly Chinese patients in the U.S. The point here is not to give an exhaustive account of relevant beliefs or to give the background to these beliefs in reference to Taoism, Buddhism, Confucianism, or folk religion. In fact, this section is undoubtedly an oversimplification of the complexity of traditional Chinese beliefs and attitudes. Further, my claim is not that all Chinese persons or all elderly Chinese persons endorse all of these views. Rather, my aim in this section is to give insight into the complexity of the web of Chinese cultural beliefs relevant to Western medical care. Because of the complexity that characterizes all bodies of cultural attitudes and beliefs (not just the Chinese), it would be extremely difficult—if not impossible—for Western physicians at medical care institutions to comprehensively study these cultural beliefs as a whole and to be ready to incorporate them in practice. As a result, medical institutions and medical careproviders may find it even more important to turn to family members to make culturally sensitive decisions.

Chinese culture is influenced by three main religions/philosophies: Taoism, Buddhism, and Confucianism. These three schools of thought intertwine in complicated ways to influence Chinese cultural beliefs and attitudes. Along with a firm Confucian devotion to familism, the Chinese (in particular, the older generations) share many different beliefs, attitudes, taboos, superstitions, et cetera, regarding the nature of medical care, the human body, sickness, death, and burial. For example, the traditional Chinese view of medicine is that it restores the balance of *yin* and *yang* (two opposing yet interconnected and interdependent natural forces) in the body, often through herbal remedies or acupuncture. As a result, elderly Chinese patients may prefer to turn to herbal remedies or acupuncture rather than to Western medicine, which they might perceive as too intrusive, unnatural, or ineffective to achieve balance of yin and yang. This preference for herbal remedies or acupuncture may seem, to an untrained eye, as noncompliant, particularly if a patient refuses to take prescription medication or undergo procedures recommended by a Western physician. Yet the Chinese patient's refusal here is more complicated than simple noncompliance; a patient's reasons for refusing can be traced back to cultural beliefs about sickness and healing and the balance of yin and yang.

Further questions may arise concerning the intrusiveness of Western medicine. A common Chinese tradition is to bury each person as a whole, with all organs intact and in place, to ensure that the spirit can travel safely to the afterlife. The ramifications of this belief for topics such as kidney removal, organ donation, and autopsies are clear. With respect to life-prolonging measures, traditional Chinese beliefs about death may be relevant. The Taoist view is that death is not an end; the soul continues to exist, and hence one ought not to fear death.[8] Buddhists believe in reincarnation and hope that subsequent rebirths will bring them closer to the achievement of Nirvana and the absence of pain and suffering.[9] The Confucian view holds that the time of death is determined by fate, and what is important is that people fulfill their duties and social responsibilities during life. Given this, life-prolonging measures (particularly invasive ones) may be rejected: "Chinese people have a strong belief in fate regarding life and death issues. . . . In the present study, participants also expressed that birth and death were parts of the life course and it was predetermined by fate. . . . Since life course is predetermined, participants believed that they had to accept whatever fate brings to life."[10] Out of profound respect for the family, life-prolonging technologies may be rejected by the elderly for fear they will burden their families.

There are traditional Chinese cultural beliefs with respect to pain and pain management. In *Concepts within the Chinese Culture that Influence the Cancer Pain Experience,* Lih-Mih Chen, RN, PhD, and colleagues introduce Taoist, Buddhist, and Confucian views of pain and pain relief:

> Within the beliefs of Taoism/energy, pain occurs if Qi, or blood circulation, is blocked. To relieve pain, the blockage of Qi/blood must be removed and the person needs to maintain harmony with the universe. Within the beliefs of Buddhism, pain/suffering is a power, unwanted but existent, that comes from a barrier in the last life;

from the objective world; from a person's own sensation; or from other people, animals, and materials. Only by following the 8 right ways (i.e., right view, right intention, right speech, right action, right livelihood, right effort, right mindfulness, and right concentration) can an individual end the path of pain/suffering. Confucianism teaches that pain is an essential element of life, a "trial" or a "sacrifice."[11]

Given these influences, elderly Chinese patients may turn to non-Western methods of pain relief, such as acupuncture. Or, given that the Confucian view is that pain ought to be endured, some Chinese may be unwilling to request pain relief directly from a medical practitioner, even when they are experiencing excruciating pain. They might be willing to speak to close family relatives about their pain to request that the relative speak to a physician on their behalf. Or they might be willing to accept pain relief if it is offered by the medical practitioner.

Cultural taboos against wearing certain colors or bringing certain types of flowers when visiting the sick also exist. For example, the colors white and blue are associated with death and mourning. Also, white chrysanthemums are symbolic of grief. Clearly, visiting an elderly relative while wearing white or blue and/or bringing white chrysanthemums would be ill advised. The elderly patient might endorse these taboos, and the Chinese-American family member, even if ignorant of these taboos, would show great disrespect if she or he were to accidentally breach these taboos.

DIFFICULTIES FOR FAMILY MEMBERS IN BRIDGING THE CULTURAL DIVIDE

With the tangled web of cultural beliefs that are relevant to the medical care of elderly Chinese patients, medical practitioners in the West must rely upon family members to make known any relevant cultural beliefs or attitudes when they attempt to provide culturally sensitive care. Family members are supposed to bridge the cultural divide. However, despite the best of intentions, family members may be unable to give medical practitioners much guidance regarding the cultural needs of elderly Chinese patients. That is, even if they embrace their duty to take care of their elderly family members and take part in the medical decision-making process, they might be at a loss because they are unfamiliar with the cultural beliefs of their family member. In particular, first-generation Chinese-Americans (and subsequent generations) who are in a position to provide care for their elderly family members who have immigrated to the U.S. may experience many barriers to fulfilling the role of cultural diplomat. Here I speak from firsthand experience as a first-generation Chinese-American who has encountered many of the barriers I describe below in trying to provide care for aging grandparents.

Although first-generation Chinese-Americans are brought up in the U.S., and, as such, undoubtedly are influenced by American values such as individualism, independence, freedom from parental authority, and so on, it is a nearly universal experience that, in the home, the Confucian virtues of filial piety and respect for one's elders are drilled into Chinese-Americans. Just as in China and Hong Kong, Chinese parents in the U.S. would do anything to help and nurture their children, and children respond with filial love and respect. Similarly, because Confucianism is deep-seated in the upbringing of first generation Chinese-Americans, they feel it is their duty to take care of elderly family members—parents, grandparents, aunts, uncles, et cetera—out of love, respect, and filial piety. This care might include taking care of the elderly in the home, rather than sending them to an institutional care facility, and coming together with other family members to make decisions about medical care, funeral preparations, burial, et cetera. Although Chinese-Americans who are raised in a Confucian household know about the general duty that they should respect their parents and elderly family members, which includes taking care of them in their old age, they may not know what Chinese customs specifically dictate in particular circumstances. The Chinese-American family member may be unfamiliar with traditional Chinese attitudes toward medicine, sickness, pain relief, or death and dying. Or, they may not know their elderly family members' wishes about end-of-life care or their attitudes toward death and dying and burial.

This lack of familiarity is a problem specific to the U.S. and other Western countries that lack a majority Chinese population. In Hong Kong and China, social norms about how to treat the elderly and the sick, Chinese attitudes toward death and dying, and cultural expectations about burial and funerary practices are not simply passed down from one generation to the next through verbal instruction. Rather, these cultural truths are absorbed by living within a community of practitioners—one lives and breathes the culture. The communal celebration of holidays and festivals help to sustain a culture, and this is true especially of the Chinese, whose culture, as influenced by Confucianism, is

highly ritualized.[12] Ritual practices convey cultural truths. For example, by participating in ritual ceremonies, Chinese demonstrate proper respect to ancestors and elders, and the rituals cement in their minds and hearts that ancestors and elders are worthy of respect. Traditional rites and customs are practiced by the entire community, and, as such, the truths that they convey need not be formally articulated in verbal instruction to those who are living within the community.

In the pluralistic and multi-ethnic U.S., however, there may not be such community support for the communal celebration of cultural festivals and holidays or for group participation in rites and rituals that transmit cultural truths about the human condition, life, death, the role of the family and the elderly, and so forth (with the exception, perhaps, of Chinatowns around the nation). Rather, within the U.S., these rites and rituals are practiced primarily within the home (if at all), which does not give first-generation (and subsequent generations of) Chinese-Americans enough opportunity to learn about traditional Chinese culture. Even more, older generations are concerned that cultural values that are passed down to younger generations are modernized and watered-down or passed down as historical interests only, rather than as truths. Most first-generation Chinese-Americans are unsure of what traditional Chinese beliefs teach about death, dying, and funerary practices, other than the very general principle that they must pay proper respect to their elders. As a result, many Chinese-Americans may be ill equipped to specify how to offer care to their elders in a way that is aligned with traditional Chinese beliefs about healing, medicine, old age, and death. Thus, even though they feel strongly that they are called, as family members, to care for their elders, they may be at a loss as to how to adequately provide this care.

Learning about Chinese attitudes toward sickness, end-of-life care, and dying through shared participation in rituals, cultural celebrations, and activities is important, because oftentimes, the younger generations are unable to ask older generations directly about these topics for a variety of reasons. First and foremost, there may be a language barrier. In the best-case scenario, a Chinese-American is fluent in the mother tongue. In the worst-case scenario, communication is severely limited because elderly patients do not speak the same language as younger family members. Perhaps a grandparent only speaks Chinese, and the grandchild who is left to care for him or her only speaks English. Or, in the most common scenario, the first-generation Chinese-American is fluent in conversational Chinese and is able to speak on a basic level about the elderly family member's medical condition. However, most American-born Chinese lack the language skills to translate in detail the complexities of the medical condition and requisite care. This language barrier makes it difficult for family members to consult elderly patients for their opinions and preferences toward medical care as shaped by their beliefs, values, and cultural background.

Setting aside any possible language barrier, there is also a cultural barrier that may prevent Chinese-Americans from asking elderly relatives for their views on sickness and eventual death. Many Chinese people are very superstitious and believe that speaking about sickness and death will bring bad luck or cause sickness or death to become imminent. In fact, speaking about death is such a taboo that even homonyms for "death" in the Chinese language are avoided. So deep is this taboo that the number four (which, in Chinese, sounds similar to the Chinese word for "death") is often considered to be an unlucky number. Although many in the younger generations no longer adhere to these taboos against speaking about death and sickness, many of the elderly are still unwilling to broach the subject of death. Or, even if the elderly are open to speaking about death, they refuse to bring up the subject for fear of alienating their children or grandchildren, or because they fear that others hold the taboo. In turn, children and grandchildren may be unwilling to broach the subject of death with elderly family members for fear of showing disrespect or upsetting them.

Lastly, Confucian familism may itself present a barrier to communication between elderly patients and their family members: patients might assume that speaking about their preferences is unnecessary because they are assured that their family members will make all the decisions for them, in accordance with Confucian filial piety. Ho describes:

> . . . the strong Confucian concept of filial piety leads parents to believe that children will make decisions for their best interests. . . . For some elderly, such beliefs also made them perceive that their children would make decisions regarding the end of life or death and dying. Therefore, for children to bring up topics such as the future death of a parent may only arouse unpleasant feelings in the family and disturb harmonious relationships. Because children are supposed to fulfill their filial responsibilities to their parents, it does not seem necessary to have discussions or make decisions in advance.[13]

Thus, if Chinese-Americans are unable to learn about the intricacies of taking care of the elderly because they (1) are unable to ask their elderly family members directly about their attitudes toward sickness and death, and (2) cannot learn about these attitudes through shared practices and rituals within a Confucian community, how are they going to make important decisions about providing care to their family members according to their wishes, culture, and beliefs?

A RETURN TO THE FAMILISTIC MEDICAL DECISION-MAKING MODEL

Given the above considerations about the difficulties that first-generation Chinese-Americans may encounter in trying to provide appropriate and respectful care for aging family members, it seems that turning to family members in the U.S. may be an insufficient guarantee of providing culturally sensitive care to elderly Chinese patients. Even if first-generation Chinese-American family members are committed to caring for elderly family members out of a deep sense of filial piety and want to provide this care in a manner that is in line with Chinese cultural beliefs, having been raised in the U.S., they may be unable to provide care to family members in the ways that Chinese culture demands. Further, they may be unable to consult elderly patients about their beliefs and opinions about their medical care, due to language or cultural barriers.

I want to clarify, however, a possible misconception about Chinese medical ethics and the familistic model of medical decision making. It is true that filial piety and respect for one's elders, according to the Confucian way of thinking, requires that the elderly are taken care of by family members and that family members participate in making decisions about an elderly patient's medical care. Yet we should not interpret this Confucian duty as one in which the family simply carries out the wishes of the elderly patient. In the Confucian system, the family is not merely an executor who, absent explicit instructions from the elderly patient, must guess what the patient would want. If this were the case, there would be little difference between a properly Chinese medical ethic inspired by Confucianism and Western medical ethics, which is centered on patients' autonomy and self-determination. In the Western model, elderly patients express their autonomy by making known their wishes about medical care. Family members or medical proxies are supposed to follow these wishes and instructions as best they can. However, in the Confucian model, elderly patients are not autonomous agents. Nor are they subject to the decisions of the family. Rather, they participate in the decision-making process with their family, if they are able and willing to do so.[14] Families, in discussing what would be the most appropriate course of action for elderly patients' medical care, do not simply discuss what patients want or would want. Rather, families discuss what they judge to be the best for the patients. While they take into consideration the beliefs, attitudes, and desires of patients, families may not honor these wishes if they deem it to be in the best interests of the patients. As Ruiping Fan notes:

> Generally, the Chinese take it for granted that the entire family makes medical decisions for a patient whether the patient is competent or not. It is the family's responsibility to pursue happiness for their loved ones as they experience a difficult time on the final path of life. If patients have particular wishes, they speak with their families. This does not mean that the family will necessarily carry out the patient's wishes. Whether the family follows the patient's wishes depends upon what the family considers the patient's best interests. The cultural assumption is that the family should make medical decisions in the best interests of the patient. If family members hold that following the patient's wishes are not for the patient's good, they will not act on such wishes. The emphasis is not placed on the patient's self-determination; rather, it is placed on the patient's good according to Confucian understanding. Accordingly, medical decisions are frequently physician-guided, family-based decisions, rather than decisions in terms of patients' self-determination.[15]

Thus, even if family members of elderly Chinese patients in the U.S. decide to request medical care for these patients in a manner that is not consistent with traditional Chinese culture and beliefs that the patients endorse, so long as family members are acting for the sake of what they see to be the patients' best interests, they are still acting in a culturally appropriate manner.

Just as cultural unfamiliarity should not be seen as an irresolvable problem in providing culturally sensitive care, language barriers may also fall away. Even if a Chinese-American family member is unable to consult an elderly patient because of a language barrier, proper understanding of the Confucian family model indicates that this is not a significant problem for the family decision-making model. The ugly truth is that most patients, even those born

in the U.S. and who are completely fluent in English, do not understand the complexities of medicine. Physicians have specialized medical knowledge, and it is not their duty to explain everything about a patient's medical condition to the patient, but to explain enough that the patient can make sound decisions. Similarly, family members need not necessarily inform Chinese patients about all of the complexities of their medical condition and the requirements of their care, particularly since translation of medical terminology can be so difficult. Rather, family members should translate as much as they can and answer as many questions as they can, so that elderly family members can participate in discussions of their medical care, if they so desire. Thus, even if patients only know about their medical condition in very general terms, the beauty of family-centered Confucianism is that they can rest assured that their family members will be looking out for their best interests and taking good care of them.

We can here create a distinction between medical decisions that are *materially* sensitive to an elderly Chinese patient's culture and those that are *formally* sensitive. Decisions that are *materially* sensitive are decisions made in accord with the patient's cultural beliefs *in regard to the content of the decision.* For example, a decision to forego prescription drugs in favor of herbal remedies, made out of respect for the patient's cultural beliefs, is a decision that is materially sensitive to culture. The decision aligns with the patient's cultural attitudes and beliefs. A *formally* sensitive decision, on the other hand, is the result of a decision-making process that is sensitive to cultural demands. A decision made by the familial whole regarding the proper course of action for the patient is a decision that is formally sensitive to the Chinese patient's culture.

What seems to be most the important to elderly Chinese patients is not that decisions about their medical care are materially culturally sensitive, but rather that they are formally culturally sensitive. Cultural and generational gaps are not common only in the U.S., but rather are universal. The elderly in Hong Kong and China are aware that the younger generations (although perhaps they are more literate in Chinese culture than their American counterparts) may not share the same beliefs and commitments, and will make decisions accordingly. Yet the elderly accept this tendency as a fact of life, knowing that their children and grandchildren will look out for their best interests. In *Perspectives on End-of-Life Decision-Making among Older Chinese,* Sio-Wa Ho concludes, from interviews conducted with a small sample of Chinese elderly in Macau, that what matters most to the elderly is that their family members will make the decision that they deem to be the best:

> Family members, therefore, will make decisions for the older parents who are sick and these decisions are believed to be of the best interest to the patients after careful considerations on the overall well-being of the patient. Sometimes, the family will disregard the patient's expressed wishes if those wishes are in conflict with the family's considerations. . . . For the participants in the present study, personal preferences were not as important as maintaining good family relationships, therefore, imposing personal preferences on the family seemed to be unacceptable. . . . Therefore, even though their wishes might not be fulfilled or respected, the participants still believed that the family had tried to do the best for the parents. As a result, they would still defer their decision-making to the family."[16]

Of course, since the study was based on interviews with 18 participants, it would be hasty to make a generalization about the willingness of Chinese elderly to subordinate their own beliefs and wishes to that of their family. Yet, Ho's findings accord with numerous other articulations of the family model of medical decision making.

Xiaoyang Chen and Ruiping Fan explain that this willingness to accept whatever the family decides is thoroughly Confucian. They write that not only is the Confucian model of medical decision making characterized by a family-centered approach, but is also characterized by the notion of harmony. They identify three analogies to describe how harmony is to be reached regarding a patient's medical care. The first analogy compares a decision to a musical performance. For harmony to be possible in a musical performance, there must be different sounds and tones. In a similar way, for harmony to be possible in decision making, there must be a variety of different viewpoints, all of which must be taken into consideration: "Similarly, in the process of decision making, the way of accomplishing a harmonious decision is not by excluding a relevant person who may hold a different view from others. Rather, all relevant persons must be involved and their diverse views respected and considered before a harmonious agreement can be made."[17]

Chen and Fan then explain how different views may be harmonized through the analogy of making a delicious soup, by bringing all the different ingre-

dients into balance. The soup-making analogy indicates that, in a decision-making process that involves, at the very least, the views of the patient, the family, and the physician (all of which may be different), each side must be willing to compromise to reach a harmonious decision about what is best for the patient. Chen and Fan explain: "The point is that in order to make a harmonious decision, relevant individuals need necessarily to adjust or compromise their original opinions so as to integrate different views and achieve a proper decision."[18] No one opinion is privileged *a priori* over others. All of the parties must be ready to consult the opinions of the other relevant parties in the decision-making process, and be willing to revise their view in light of the opinions of others.

In being ready to compromise in order to work for what is best for the patient, the parties to the discussion demonstrate their commitment to Confucian virtue, which brings us to the third analogy identified by Chen and Fan. The third analogy compares a decision-making process to the pursuit of good health, which is a combination of bodily harmony, mental harmony, and life-process harmony. These three harmonies can be achieved only when one acts according to virtue—doing the right thing at the right time and in the right way. Chen and Fan summarize:

> Although the point of the soup-cooking analogy is that different opinions must be coordinated, integrated, adjusted, and compromised in order to achieve a harmonious decision, the point of this health-pursuing analogy is that such coordination, integration, adjustment, and compromise should not be done arbitrarily or as a result of social or political coercion. Rather, decisions should be made under the guidance of virtue, in just the same way in medical decision making (the patient, family members, and physician) attempts to solve their disagreements.[19]

In other words, for all the different opinions to be harmonized, all of the different parties must seek resolution in accordance with virtue.

In sum, family members in the U.S. may not be able to make medical decisions for their elderly family members that are in line with traditional Chinese culture in terms of content. Still, by being involved in the decision-making process, these family members are making decisions that are in line with the form of traditional Chinese culture. The Chinese elderly are prepared to make their own wishes regarding medical care subordinate to the wishes of their family members.

FURTHER SUGGESTIONS

Even if medical practitioners and institutions can rely upon the family medical decision-making model as the primary vehicle to provide culturally sensitive care to elderly Chinese patients since materially sensitive decisions are less important than formally sensitive decisions, we should still strive for better cultural literacy. As Chen and Fan explain, true harmony in medical decision making demands that the views of all parties be taken into consideration, including the cultural views of elderly Chinese patients. If patients are unable or unwilling to voice their views and beliefs, then their family members might wish to learn more about Chinese cultural attitudes toward, or taboos regarding, sickness, death, and dying for the sake of a harmonious decision. The question then becomes how to meet demands for cultural literacy.

The easiest solution, of course, would be to discuss these issues directly with elderly relatives, preferably well before hospitalization or serious illness. A family discussion with all relevant parties, to gauge the elderly patients' preferences and beliefs concerning medical care and advanced planning will make things easier for the family when sickness actually strikes. Further, such discussions will allow families to have a "game plan" in the eventual case of sickness, hospitalization, or death. Younger relatives should carefully approach elderly patients to test whether they would be open to having such discussions. Such an approach has the advantage of determining how closely elderly relatives share traditional Chinese views. It may be that patients believe all of the traditional Chinese views and superstitions concerning sickness, medical care, death, and burial. But they might adhere to some and not others. Or, on closer examination, they may not believe any at all. If elderly relatives are amenable, it would be wise for family members to request that they make clear their wishes in the form of some sort of advanced directive, so that their views may be discussed and harmonized with the views of the rest of the family.

But what about when elderly relatives refuse to do any sort of advanced planning, because of strict adherence to the taboo against speaking about death or sickness? Or when an elderly relative is incapacitated and unable to state his or her views concerning the matter, yet family members assume that their relative adheres to traditional Chinese views regarding sickness and death, views with which the family is unfamiliar? One possible solution is that, just as hospitals and communities have translators to

help with any language barriers that the elderly may confront when seeking medical care, perhaps communities should seek Chinese cultural diplomats who would be willing to offer general advice and explanations about traditional Chinese beliefs about sickness, death, old age, and other such relevant topics. Perhaps there might be a member of a local senior citizens' center, or Chinese cultural organization, who is willing to talk about these topics and would be open to volunteering time to speak to concerned family members, or to serve as a liaison between elderly patients and their family. Of course, such an approach is more feasible in communities with a large Chinese population, such as San Francisco, Vancouver, or Los Angeles. Despite the limitations in scope, however, this endeavor would be worthy of pursuit.

Perhaps, simultaneous with some sort of "cultural diplomat" program to serve as a reference for younger Chinese-Americans who want to become familiar with Chinese attitudes and customs, community-wide programs could be created to shift existing taboos against talking about death. Carol K.L. Chan and Matthew K. Lau describe one such effort that has met with some success in Hong Kong:

> In Hong Kong, a predominantly Chinese community, taboos associated with death have been successfully challenged with the establishment of a societal-wide campaign, the ENABLE project. The ENABLE project conducts experimental workshops and training programs at different levels to educate the general public and professionals in the healthcare, hospice, social work, and family services sectors on making effective death preparation. . . . The project is spearheaded by academics from healthcare and social work, and is funded by a local charitable trust. The goal of the project is to aid individuals in adjusting to bereavement and loss in end-of-life by means of encouraging the elderly and their family to talk about death, as well as prepare for it.[20]

While cultural diplomats could help younger generations to understand the mindset of the older generations regarding sickness and death, programs geared toward encouraging the elderly to engage in advanced healthcare planning would help them to adjust their attitudes and come to a compromise, thereby bringing about harmony between the generations.

Further, the elderly may be amenable to speaking about death and dying with a disinterested third party who is not a family member. By doing so, they may not need to fear that speaking about death will bring bad luck to the family. Ho writes:

> Since talking about death with family may not be appreciated in the family because of the cultural beliefs, talking to unrelated people therefore becomes a way for older people to express their concerns about the approaching death. Though it is said that death should be accepted as it is predetermined, concerning about it as it is part of life is not an abnormal behavior. Hence, discussing about their attitudes toward death and dying with the researcher, as an unrelated person to them, is considered not to be a taboo.[21]

These community programs could provide the elderly with non-family members to whom they could express their beliefs and wishes concerning medical care and end-of-life planning.

So far, my suggestions have been aimed at helping elderly patients in the U.S. and their family members make culturally sensitive decisions about medical care. After all, the burden of making medical care culturally sensitive seems to lie with patients and their family members, rather than with physicians and hospitals, given the complexity of culture and that each individual embraces cultural beliefs and values to different degrees. Yet, as the DHHS Office of Minority Health and institutions of medicine make increased requirements for cultural sensitivity, we must give greater thought to how to provide culturally appropriate medical care. We can start with increased sociological research on the beliefs and attitudes of the elderly Chinese immigrant population in Western countries, and also with philosophical study tracing how Confucianism, Taoism, and Buddhism influence the attitudes and beliefs of the elderly Chinese population with regard to issues relevant to medical and end-of-life care. To date, systematic studies of these topics has been scarce, as Ho points out:

> Few studies have been conducted in Chinese societies on older people . . . and little is known about these older people's perspectives on their end-of-life decisions. . . . Conducting research in the Chinese cultural context can give in-depth insight into how older Chinese people make decisions on end-of-life issues. Understanding older people's care and treatment preferences at their end-of-life may help family or professionals to fulfill final wishes of the dying persons, to reduce the stress and burden put upon family members when they have to face difficult end-of-life situations for their loved ones, to promote well-being of patients and family and

to implement better services and interventions to meet their needs."[22]

Studies on the elderly Chinese immigrants in the U.S. are even more scarce, and such studies would greatly help to meet the demands for cultural sensitivity in medicine.

NOTES

1. U.S. Department of Health and Human Services Office of Minority Health, "National Standards for Culturally and Linguistically Appropriate Services in Health Care," March 2001, *http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15,* accessed 1 November 2013.

2. Ibid.

3. In this article, I focus on the issue of providing culturally sensitive medical care to elderly Chinese patients who have immigrated to the U.S. The reason for this narrow focus is that traditional Chinese beliefs (particularly those that I describe in the section "Cultural Beliefs and Attitudes Relevant to Medical Care" in this article, among others) are most likely to be strong within this very small subset of the Chinese population in the U.S. Younger generations, in Hong Kong, China and the U.S., for example, are less likely to strongly hold traditional Chinese beliefs concerning life and death, sickness, and healing care, which leads to the cultural divide that I later describe.

4. X. Chen and R. Fan, "The Family and Harmonious Medical Decision Making: Cherishing an Appropriate Confucian Moral Balance," *Journal of Medicine & Philosophy* 35, no. 5 (October 2010): 576-86, 576.

5. R. Fan, "Informed Consent and Truth Telling," *HEC Forum* 12, no. 1 (March 2000): 87-95.

6. Ibid., 92.

7. The University of Washington Medical Center, for example, has published "Communicating with Your Chinese Patient," *http://depts.washington.edu/pfes/PDFs/ChineseCultureClue.pdf,* accessed 23 April 2013.

8. S.-W. Ho, "Perspectives on End-of-Life Decision-Making among Older Chinese" (PhD dissertation, North Dakota State University of Agriculture and Applied Science, 2008), 47.

9. Ibid., 48.

10. Ibid., 57.

11. L.-M. Chen et al., "Concepts Within the Chinese Culture that Influence the Cancer Pain Experience," *Cancer Nursing* 31, no. 2 (March-April 2008): 103.

12. Chen and Fan, see note 4 above.

13. Ho, see note 8 above, p. 58.

14. Fan, see note 5 above, p. 90.

15. Ibid.

16. Ho, see note 8 above., pp. 31-2.

17. Chen and Fan, see note 4 above, pp. 580-1.

18. Ibid., 581-2.

19. Ibid., 583.

20. ENABLE is an acronym for the Empowerment Network for Adjustment to Bereavement and Loss in End-of-life. C.K. Chan and M.K. Yau, "Death Preparation Among the Ethnic Chinese Well-Elderly in Singapore: An Exploratory Study," *OMEGA* 60, no. 3 (2009-2010): 228.

21. Ho, see note 8 above, p. 62.

22. Ibid., p. 17.

Patients' Experiences with Disclosure of a Large-Scale Adverse Event

Carolyn D. Prouty, Mary Beth Foglia, and Thomas H. Gallagher

ABSTRACT

Background

Hospitals face a disclosure dilemma when large-scale adverse events affect multiple patients and the chance of harm is extremely low. Understanding the perspectives of patients who have received disclosures following such events could help institutions develop communication plans that are commensurate with the perceived or real harm and scale of the event.

Methods

A mailed survey was conducted in 2008 of 266 University of Washington Medical Center (UWMC) patients who received written disclosure in 2004 about a large-scale, low-harm/low-risk adverse event involving an incomplete endoscope cleaning process. The survey measured patients' satisfaction with this disclosure, their concerns about healthcare outcomes, and their recommendations for future communication, given similar circumstances.

Results

Surveys were received from 127 of 266 (48 percent) of eligible respondents; 98 percent thought that UWMC was right to inform them about this event, and mean satisfaction with the disclosure was 7.7 on a 0 to 10 scale. Of the 127 respondents, 64 percent were somewhat or very concerned that the endoscope cleaning problem might cause them health problems; 60 percent reported their impressions of UWMC's honesty and integrity had increased; 31 percent said their perceptions of the quality of care had increased; 94 percent agreed that institutions should tell patients about any error in their care, even when the risk of harm was low, although 28 percent agreed that such notifications would make them anxious. Respondents who reported concern that the event could cause them health problems were less likely to be satisfied with the institution's disclosure. Patients cited their right to know information material to their own health and healthcare as an important reason for disclosure.

Conclusion

Recipients of disclosure of a large-scale, low-harm/low-risk event overwhelmingly supported being told of the event and endorsed notification of patients for similar events in the future. Although informing patients may cause concern for some, institutions should ensure their disclosure policies and procedures reflect their patients' preferences.

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There is widespread agreement that patients have a compelling interest in being told about harmful medical errors in their care. The ethical justifications for disclosure of harmful medical errors involving an individual patient have been well described,[1] and include respect for patients' autonomy, informed decision making, and careproviders' professional obligation to be truthful. These essential elements of medical ethics are integral to patient-centered care, and ensure that patients have full knowledge of events in their healthcare. Additionally, disclosure strengthens patients' perceptions of the quality of healthcare provided, and helps identify opportunities to prevent future errors.

To date, most research on institutional disclosures envisions situations in which an individual patient is affected by an adverse event.[2] However, situations do occur in which a breakdown in the care process affects multiple patients; these have been termed "large-scale adverse events" (LSAEs).[3] These events are not uncommon; publicly described events have affected well over 100,000 patients, with varying levels of harm.[4]

The decision whether, and how, to disclose an LSAE to potentially affected patients is complex, particularly in situations in which the probability that patients have been harmed is extremely low. Studies examining patients' preferences suggest they favor disclosure any time an error has caused harm.[5] Yet patients have more mixed opinions regarding learning about "near-miss" errors in their care (errors that did not cause harm): some wanted to know, while others think it would make them nervous.[6] Low-harm/low-risk LSAEs are likely to resemble near misses, since most patients will not experience physical harm from the exposure itself. Thus, there is genuine uncertainty about patients' disclosure preferences in the case of low-harm/low-risk LSAEs.

Institutions may have important reasons to be reluctant to disclose LSAEs for which the risk is very small. Institutional leaders may wonder if the anxiety produced by learning of such events would outweigh patients' desire for disclosure. Additional factors complicating these LSAE disclosure decisions include difficulty in identifying and contacting patients, potential litigation, negative publicity, and loss of reputation and public trust.[7]

Understanding the preferences and experiences of patients who have been the recipients of an actual LSAE disclosure could provide helpful information to institutional leaders contemplating how to respond to future LSAEs. While research is beginning to explore patients' and family members' experiences with actual disclosures to individual patients,[8] to our knowledge no prior studies have examined the perspectives of patients who have actually experienced a disclosure of an LSAE and their recommendations for how communication about future LSAEs should be handled.

In February 2004, staff at the University of Washington Medical Center (UWMC) noticed a shortened cleaning cycle in one of their newly installed endoscope cleaners. Subsequent investigation revealed that, over the previous three months, nearly 600 patients had gastrointestinal endoscopy procedures using incompletely cleaned equipment. Although the risk of infection associated with the use of such equipment was estimated to be no more than baseline for such procedures, approximately one in 1.8 million,[9] the UWMC, following deliberation amongst medical staff, administrative leaders, and ethicists, opted to immediately disclose the endoscope cleaning problem, in writing, to all affected patients. The letter contained an explanation of the event, the estimated risk of infection, and instructions for how to obtain further information. The letter did not mention specific diseases that patients may have been exposed to or provide options for obtaining testing. UWMC created a special hotline where affected patients could call with questions, a detailed protocol for responding to these queries, and issued a news release about the event.[10]

In July 2008, we surveyed these patients to assess the impact of this LSAE disclosure, its effects on their impressions of the institution's honesty, integrity, and quality of care, and to learn their recommendations for disclosure, should a similar event occur in the future.

METHODS

Study Purpose

The purpose of this study was to characterize patients' satisfaction with disclosure practices among individuals who had received a disclosure of an actual low-harm/low-risk LSAE. Two additional goals were to compare the responses of patients who were concerned about a potential health impact from the LSAE to those who were not, and to qualitatively describe patients' reasons in support of or against disclosure of similar events in the future.

Data Collection Methods

A 14-question survey consisting of open and closed ended questions was developed by two of the authors (TG and CP), in consultation with UWMC leaders and risk managers. A cover letter

briefly explained that UWMC was interested in learning about the recipients' reaction to how the LSAE was disclosed to them and their recommendations regarding communication about events such as these in the future. Respondents were initially asked: (1) if they recalled receiving the original letter; if so, (2) if the letter provided them with sufficient information; (3) if, after reading, they were concerned that the cleaning problem might cause them health problems; and (4) if they thought, at the time, that UW was right to inform them. A sealed envelope with the original disclosure letter was included with the survey. All respondents were asked to read the disclosure letter in the sealed envelope and answer the remaining survey questions concerning satisfaction with UWMC's communication; the effects of the disclosure on beliefs about UWMC's honesty, integrity, and quality of care; and recommendations for disclosure in any similar future episode.

The anonymous survey of exposed patients was conducted between August 2008 and July 2009. Informed consent was implied by returning the survey. The survey was mailed from the medical director's office to the known current addresses of patients, including a card to decline participation. The original disclosure letter had been translated into Spanish, Vietnamese, Russian, and at least three other languages for non-English-speaking patients; these patients did not receive the survey. Participation (completing the survey) was encouraged through repeated mailings and telephone calls. There was no incentive provided for participation. The University of Washington Institutional Review Board approved this project.

Data Analysis

Data from the surveys were entered and analyzed using the Statistical Package for the Social Sciences 18.0 for Windows with the statistical significance set at .05 for all comparisons. Our first aim was to characterize patients' perceptions regarding how this endoscopy LSAE was disclosed to them. Descriptive statistics were calculated for each item in the survey to establish overall response distributions. A second aim was to compare the responses of patients who were concerned about a potential health impact with those who were not concerned about a health impact from the LSAE. One-way analysis of variance (ANOVA) and *post hoc* tests were used to establish which groups differed significantly from one another on a particular response. We applied the Scheffe *post hoc* test to significant findings. A final aim was to examine the relationship between patients' characteristics and their responses to survey items. One-way analysis of variance and *post hoc* tests were used to explore differences in responses based on age and educational level.

Responses to the open-ended questions were coded by one investigator (CP), using conventional content analysis to identify major themes.[11] These themes were validated by another investigator (TG); inter-rater differences were resolved by consensus.

RESULTS

Response Rates and Sample Characteristics

We sent 544 surveys to patients at the addresses listed at the time of their endoscopy. Of these, 278 were found to be ineligible, because they were deceased, they indicated to researchers that they were unable to sufficiently comprehend written English, their survey was undeliverable and they were not able to be reached by phone to confirm a different address, or other reasons. These left 266 eligible respondents, from whom we received 127 surveys, yielding a response rate of 47.7 percent (figure 1).

Sample characteristics for this study are summarized in table 1. Nearly 85 percent of the respondents were White, followed by Asian (9 percent), and African-American (3 percent). All respondents had some type of health insurance coverage; 12 percent had a four-year college degree, and nearly 45 percent of the respondents had more than a four-year college degree.

Survey Responses

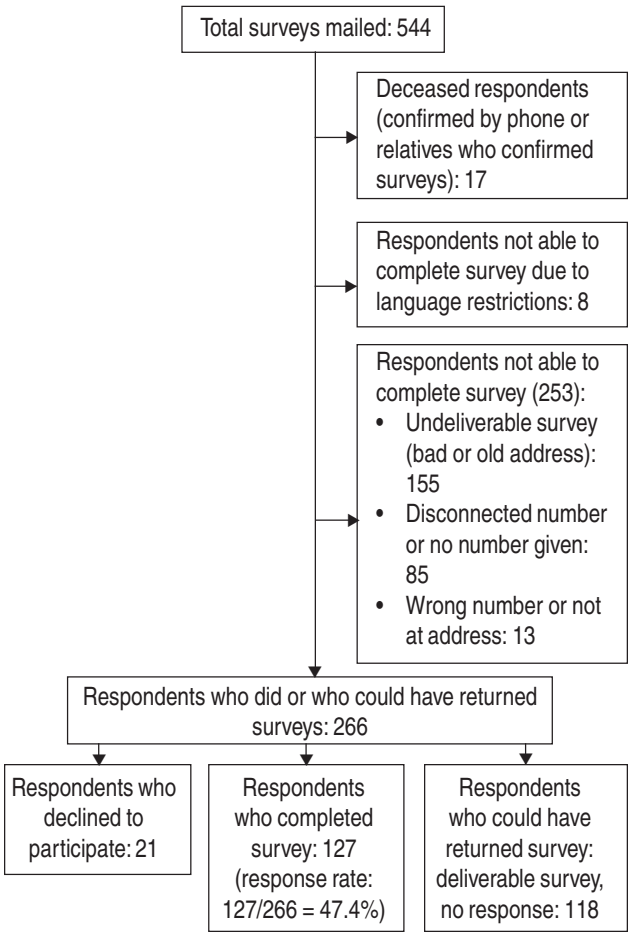
The overall response distribution of the sample is summarized in table 2. More than 80 percent of the respondents recalled having received a letter from UWMC that disclosed the problem with endoscope cleaning equipment. Of the respondents who recalled receiving a letter, 90 percent thought the letter provided them with the information they needed to understand the event. More than 98 percent of the respondents who recalled receiving a letter, thought that UWMC was right to inform them about the problem at the time. A majority of respondents who recalled receiving the letter was either "very concerned" (15 percent) or "somewhat concerned" (49 percent) that the problem with the endoscope cleaning might cause them health problems.

Of the 127 respondents, 60 percent reported that this disclosure experience increased their impression of UWMC's honesty and integrity. While 22 percent said their impression regarding the quality of care provided by UWMC had decreased due to this experience, more than 30 percent of the respondents reported their impression of the quality of care

had increased. Of the respondents, 11 percent reported they had contacted the medical center for more information about what had happened, and 8 percent reported they requested to be tested for potential infections after this event. Mean satisfaction with the way in which UWMC communicated with respondents about the event was 7.7 (SD = 2.431) on a scale in which 0 equals "extremely dissatisfied" and 10 equals "extremely satisfied."

When asked how such events should be handled in the future, more than 90 percent of the total respondents "strongly agreed" or "somewhat agreed" that medical centers should tell patients about an error in their care, even if the chance of harm is extremely low. Furthermore, more than 97 percent of respondents thought that if a similar episode happened in the future, healthcare organizations should inform patients about what happened. However, 28 percent "agreed strongly" or "agreed somewhat" that it would make them nervous to be told about an error in their healthcare, even if the chance of harm is extremely low.

FIGURE 1. Flow chart of survey collection data.



Comparisons between Respondents Based on Concerns about Health Outcomes

Further data analysis was conducted to explore whether survey responses differed based on how concerned respondents were that the problem with the endoscope cleaning equipment might cause health problems. The respondents who recalled receiving the disclosure letter were classified into three groups according to whether they were "not at all concerned," "somewhat concerned," or "very concerned" that the problem with the endoscope clean-

TABLE 1. Respondents' sociodemographics (*N* = 127)

	n	Valid %
Age (*n* = 122)		
25-34	2	1.6
35-44	2	1.6
45-54	20	16.4
55-64	54	44.3
65-74	28	23.0
75 or older	16	13.1
Highest grade level achieved (*n* = 120)		
8th grade or less	1	0.8
Some high school	3	2.5
High school graduate or GED	13	10.8
Some college or 2-year degree	36	30.0
4-year college graduate	14	11.7
More than 4-year college graduate	53	44.2
Are you Hispanic or Latino? (*n* = 117)		
Yes	1	0.9
No	116	99.1
Race/ethnicity (*n* = 118)		
White	98	83.1
Black or African-American	4	3.4
Asian	11	9.3
American Indian	2	1.7
Other	3	2.5
Insurance (*n* = 119)		
Medicare or Medicaid	27	22.7
Employment-related	45	37.8
Washington State Basic Health Plan	7	5.9
Private	24	20.2
Medicare or Medicaid and employment-related	7	5.9
Medicare or Medicaid and private	7	5.9
Medicare or Medicaid and Washington State Basic Health Plan	2	1.7

TABLE 2. Overall response distribution (*N* = 127)

Survey item	Response categories	*n*	Valid %
Do you recall having received a letter in 2004 about the problem with the endoscope cleaning equipment? (*n* = 127)	Yes	103	81.1
	No	24	18.9
If yes, did the letter provide you the information you needed to understand this event? (*n* = 103)	Yes	93	90.3
	No	10	9.7
After reading this letter, were you concerned that the problem with the endoscope cleaning equipment might cause health problems for you? (*n* = 104)	Not at all concerned	37	35.6
	Somewhat concerned	51	49.0
	Very concerned	16	15.4
At the time, did you think UWMC was right to inform you of this problem? (*n* = 103)	Yes	101	98.1
	No	2	1.9
(After reading letter): Does the letter provide you the information needed to understand this event? (*n* = 121)	Yes	110	90.9
	No	11	9.1
How did this experience affect your impression of UWMC regarding their honesty and integrity? (*n* = 124)	Decreased a lot	1	0.8
	Decreased a little	7	5.6
	No change	42	33.9
	Increased a little	38	30.6
	Increased a lot	36	29.0
How did this experience affect your impression regarding the quality of care provided by UWMC? (*n* = 124)	Decreased a lot	9	7.3
	Decreased a little	18	14.5
	No change	59	47.6
	Increased a little	16	12.9
	Increased a lot	22	17.7
On a scale from 0 to 10, where "0" is "Extremely Dissatisfied" and "10" is "Extremely Satisfied," how satisfied were you with the way that UWMC communicated with you about this event? (*n* = 121)	0 = Extremely dissatisfied (0 to 1)	2	1.7
	2	4	3.3
	3	3	2.5
	4	1	0.8
	5	17	14.0
	6	6	5.0
	7	8	6.6
	8	25	20.7
	9	16	13.2
	10 = Extremely satisfied	39	32.2
Imagine that a similar event happens in the future, where an error occurs that affects many patients but that has very little chance of causing harm to these patients. Do you agree or disagree with the following statements?			
a. Medical centers should tell patients about any error in their care, even if the chance of harm is extremely low. (*n* = 123)	Disagree strongly	1	0.8
	Disagree somewhat	6	4.9
	Agree somewhat	14	11.4
	Agree strongly	102	82.9
b. It would make me nervous to be told about an error in my healthcare, even if the chance of harm is extremely low. (*n* = 120)	Disagree strongly	74	61.7
	Disagree somewhat	12	10.0
	Agree somewhat	26	21.7
	Agree strongly	8	6.7

TABLE 2 *(continued)*

Survey item	Response categories	*n*	Valid %
All things considered, if a similar episode happened in the future, would you recommend that organizations like UWMC: (*n* = 118)	Inform patients about what happened	115	97.5
	Not inform patients about what happened	3	2.5
	*Marked both "Inform" and "Not inform"**	*5*	
At the time of the event, did you contact the medical center for more information about what had happened? (*n* = 120)	Yes	13	10.8
	No	97	80.8
	Not sure	10	8.3
Did you request to be tested for potential infections after this event? (*n* = 117)	Yes	9	7.7
	No	103	88.0
	Not sure	5	4.3

Note: The total number of responses per item varies with the number of respondents who left the question blank.
* Five respondents checked both boxes, and provided written reasons for both why to and why not to inform patients.

TABLE 3. ANOVA comparisons: level of concern about health outcomes

				Group differences		Group means	
Survey item	d.f.	F-ratio	*p*-value	Groups*	*p*-value	Group	Mean score
Letter provided information needed to understand event (for those who remembered receiving the letter)	101	11.83	.000			N	1.00
						S	1.08
						V	1.40
Affected impression of quality of care provided	101	6.719	.005	N-S	.005	N	3.65
						S	2.86
						V	3.07
Satisfaction with the way UWMC communicated	98	26.696	.003	N-V	.005	N	8.85
						S	7.80
						V	6.67
Nervous to be told about an error in my healthcare, even if chance of harm is extremely low	96	3.126	.05	N-S	.03	N	1.38
						S	1.88
						V	2.00
Requested to be tested for potential infections	95	4.071	.020			N	2.00
						S	1.96
						V	1.69

Note: d.f. = degrees of freedom. N = Not at all concerned. S = Somewhat concerned. V = Very concerned.
* Even though the F-ratio was significant, not all of the pair-wise group comparisons were significant due to the stringency of the *post-hoc* tests in avoiding Type 1 error. The F-ratio is used to determine whether the variances in two independent samples are equal.

ing equipment might cause health problems. The ANOVA results and *post* hoc tests for multiple group comparisons are summarized in table 3.

There were significant group differences based on whether participants believed the notification letter provided the information they needed to understand the event, their impressions of the quality of care provided by UWMC, their satisfaction with the way UWMC communicated about the event, whether the respondents requested testing, and whether respondents would be nervous to be told about an error in healthcare, even if the risk was low. Even though the F-ratio was significant, not all of the pair-wise group comparisons were significant due to the stringency of the *post-hoc* tests in avoiding Type 1 error. A means plot for each comparison suggested that responses were in the expected direction. Respondents who were "somewhat" or "very concerned" that the adverse event might cause problems with health outcomes reported less-favorable responses to whether the notification letter provided needed information, lower impressions of the quality of care provided by UWMC, greater nervousness over being told about an error, and lower levels of satisfaction with the way UWMC communicated about the event.

Comparisons between Respondents Based on Select Demographics

Analyses were also conducted to explore whether survey responses differed based on select demographics. Respondents with less education (a high school diploma, GED, or less) were more likely than respondents with more education (some college or two-year degree, four-year college degree, or more than a four-year college degree) to agree that it would make them nervous to be told about an error in their healthcare, even if the chance of harm is very low. Respondents who were 65 years of age or older were more likely than respondents between the ages of 45 and 64 years of age to report that their impression of the quality of care at UWMC had increased as a result of the disclosure.

Reasons for and against Disclosure

Respondents were asked if they would recommend that organizations like UWMC inform or not inform patients, should a similar episode happen in the future, and to provide the most important reason that they would or would not recommend this. Respondents gave numerous reasons (133 total responses) for recommending that patients be informed, including wanting/having the right to personal healthcare information, concerns about risk, and desires for honesty, integrity, trust, and confidence in the institution. Sample responses are listed in table 4. The most commonly given reason for recommending not informing patients, of eight total responses, was the low risk of infection.

COMMENT

Large-scale adverse events, and their associated media coverage, create public concern about healthcare quality and pose challenges for healthcare institutions around disclosure. One key question healthcare leaders face when contemplating disclosure of such events is whether patients would believe that the anxiety created by the notification would outweigh the benefits of being told what happened. Our study, the first to assess the experiences and recommendations of patients who have been the actual recipients of an LSAE disclosure, highlights patients' unequivocal support for such disclosure.

The overwhelming majority (98 percent) of these patients thought that the institution was right to disclose the problem, were satisfied with the disclosure (7.7 on a scale of 10), and strongly supported future disclosure of similar events (98 percent). The most common rationale patients cited for recommending disclosure was their right to know—almost half of the comments received from patients emphasized that they needed and wanted information relevant to their own health. A smaller number cited honesty, integrity, and confidence in healthcare institutions as the most important reasons for disclosure, findings consistent with existing literature on the benefits of disclosure.[12] Previous studies have affirmed patients' preferences to be told of medical errors in their care as individual patients,[13] and our findings suggest that those preferences extend to large-scale, low-harm adverse events as well.

Despite institutional unease about negative publicity and loss of public trust, the majority of patients in this study had an improved perception of the institution's honesty and integrity. Other research found no long-term impact on use of the hospital after public investigation of such incidents,[14] and multiple studies indicate that patients and families believe that disclosure may improve relationships with careproviders.[15] These collective findings provide compelling evidence for institutions to disclose even low-harm/low-risk LSAEs to patients, as the benefits of these disclosures appear to outweigh institutions' concerns.

Although support for disclosure was extremely high, an important subset of patients expressed some

anxiety about potential health problems. Nearly 30 percent said it would make them nervous to be told, and a small proportion contacted the hospital after disclosure, including a few who asked for testing. Those who were more concerned about health impacts were the least satisfied with how the disclosure was conducted, with the adequacy of the information the letter provided, and had decreased impressions of the quality of care. Research in risk perception may help to explain these patients' experiences. Perception of risk is determined by a number of factors including dread of the outcome, whether the risk is voluntary or imposed, and familiarity with the risk.[16] Risks that are dreaded and out of one's control tend to be overestimated,[17] and a lack of knowledge of probability and scale can also hamper risk perception, even in a highly educated cohort, such as the subjects of this study.[18] It is also important to note that patients and experts apply different paradigms when assessing risk.[19] For example, uncertainty is accepted by experts, but in lay people this can increase perception of risk.

Concerns about disclosure causing increased anxiety in patients have been used by institutions as a reason not to disclose.[20] However, even these concerned respondents agreed patients should be told about any error in care and recommended disclosure for any future error similar to this one.

These findings highlight the importance of organizations' use of thoughtful, multi-modal approach to communicating with patients affected by large-scale adverse events, taking into account pa-

TABLE 4. Sample of responses: reasons to inform or not inform patients about large-scale adverse events (LSAE)

Text from the survey*:* All things considered, if a similar episode happened in the future, would you recommend that organizations like University of Washington Medical Center:

- Inform patients about what happened?
- Not inform patients about what happened?
- What is the most important reason you would recommend this?

Reasons given for why to inform patients of LSAE (total number of comments: 133):

Patients' right/desire/need to know information for their own health (54 comments):

- The right of patients to know about anything that might impact the quality of their care.
- So that any untoward health developments could be recognized and tested.
- It may make me anxious but is also my right as a patient to know.
- Knowledge gives a person the ability to make sound decisions regarding their medical care.
- It is my body—I have a right to know what was done.

Honesty, integrity (15 comments):

- It demonstrates integrity and good faith.
- I want to know that errors in care are communicated. I would be more concerned to think that errors are being made and covered up.
- It goes to the overall integrity or trustworthiness of the institution.

Confidence in institution (12 comments):

- Helps patients understand how much effort and level of care goes into a specific procedure.
- It's an indicator that UW is diligent about maintaining high standards.
- It would increase my confidence in the UW medical center. Errors happen, being open and honest about them indicates that patient welfare is the UW primary interest.

Trust (6 comments):

- Trust in the personnel giving me the best healthcare possible.
- It builds trust, that UW won't try to hide important information from me.
- Maintaining my trust in the UWA Medical Center. No one is perfect and the most important thing is open and honest communication. I like information!

Reasons given for why *not* to inform patients of LSAE (total number of comments: 8):

- If there is no appreciable risk.
- The chance of risk if very low. To inform this would make some people nervous and no advantage.
- Since there was no increased risk, I don't see any reason to inform patients.
- Scares old people.

tients' characteristics such as health literacy, language spoken, and level of anxiety, and including explicit plans to provide free follow-up diagnostic testing and treatment. For events for which the probability of harm is higher or when the affected patient is anxious and concerned about health outcomes, institutions should undertake additional measures such as notifying or following up with patients individually via treating physicians and providing emotional and clinical support through qualified healthcare professionals.[21]

Institutions may also benefit from consulting with risk communication experts when planning communication and follow up. Risk communication is the science of communicating health risk under conditions of high public concern and uncertainty, and when there are differences in interpersonal power between the parties involved in the event. This literature recognizes the psychological, social, and cultural contexts that shape patients' risk perceptions, as well as their emotional and informational needs.[22] The content of disclosure communications should address what the patients want to know, what careproviders deem to be critical, as well as what is likely to be misinterpreted if not explained. Perception of uncertainty increases with changing or incomplete information, and when unfavorable information appears at the end of a letter.[23] Integrating knowledge of risk communication, infectious diseases, ethics, and disclosure into a disclosure of a large-scale adverse event is complex and resource intensive, but may pay off in the long run by preserving the patients' and the public's trust in the integrity of the healthcare institution and its staff.

The recent experience of the Everett Clinic, in Everett, Washington, with an LSAE disclosure highlights the benefits of a thoughtful, proactive approach.[24] The clinic discovered that, during an eight-month period in 2012, more than 2,000 patients were potentially exposed to a fungus *Acremonium,* due to contamination of equipment used during evaluation for chronic sinusitis. While *Acremomium* exposure does not usually cause infection in patients with normal immune systems, patients with weakened immune systems could be at additional risk of sinus infection. As soon as the problem was identified, the clinic worked closely with experts in infectious disease, ethics, communication, and patient safety, as well as with state public health agencies, to formulate a comprehensive approach to identifying and fixing the problem and to notifying affected patients. The clinic developed customized notification letters based on whether a patient had previously had a prior sinus culture, and, if so, whether that culture was positive or negative for *Acremonium*, and then mailed 2,200 letters at approximately the same time that a press release was provided to the media. A hotline was established at the clinic that patients could call for more information, along with a dedicated *Acremonium* clinic. Both the letter to patients and the press release expressed the clinic's regret about what had happened. The resulting media coverage lasted for one day, was balanced, and the story in the *Everett Herald* newspaper included a comment from a local public health officer noting, "I feel they've taken all appropriate steps."[25]

There are several limitations to this study. Although we attempted to maximize the number of respondents, the time between the event and its disclosure in 2003/2004 and the survey in 2008 made it impossible to contact many who received the original disclosure. Also, given the time between the disclosure and the survey, respondents' memories and attitudes may have changed due to recall bias. *Recall bias* can be found in any study that asks participants to reflect on a past event or experience, and subsequent experience may color the participants' current beliefs and attitudes. However, what is compelling in this study is the near universal agreement in the necessity of disclosure of a low-harm/low-risk LSAE. Additionally, those who responded to the survey were largely White, well-educated, and could read English, and may not be typical of a more representative sample of the patient population, but research on patients' preferences for disclosure of (hypothetical) individual errors, using a larger and more diverse sample, found no relationship between disclosure preferences and patient race/ethnicity, gender, age, or education level.[26] Given our respondents' unequivocal endorsement for disclosure, we expect that our results would be replicated in more diverse populations. However, more study is required to improve our understanding of how to shape disclosure to meet the needs of specific patient groups.

While much ground has been gained in the movement toward transparency in healthcare, there is still a great deal of progress to be made. Patients' preferences, coupled with the ethical analysis of disclosure of large-scale adverse events,[27] create an unambiguous argument in favor of disclosure. Institutions should develop policies that are guided by these findings to ensure full transparency with patients when LSAEs with low levels of risk occur. Careful planning is warranted in the delivery of the disclosure, as some patients will have health concerns that may cause them to lose trust in the organization. Future study should explore which com-

munication strategies best support patients who are anxious about an LSAE's impact on their health, and how LSAE communication strategies should account for variation in the nature and degree of harm of these events. While the process required for an effective large-scale adverse event disclosure may be lengthy and even uncomfortable, the benefits of transparent communication on patients' and the public's perceptions of trust and quality of the institution highlight the importance of pursuing this path of openness.

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DISCLAIMER

The views expressed herein do not necessarily represent the views of the Department of Veterans Affairs or the U.S. government.

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Organ Donation

Organ Donation among Undocumented Hispanic Immigrants: An Assessment of Knowledge and Attitudes

Joshua S. Baru, Brian P. Lucas, Carmen Martinez, and Daniel Brauner

ABSTRACT

Background

Undocumented immigrants can donate their organs, but lack access to organ transplantation. This challenges foundational principles of organ donation: fairness and informed consent. Little is known about undocumented immigrants' knowledge of barriers to their access to organ transplantation or how this might affect their decision to donate their organs.

Methods

The study was performed in an urban, university-affiliated, safety-net hospital. We interviewed hospitalized patients who self-identified as undocumented immigrants and were unaware of having any contraindication to organ donation (for example, cancer). We first recorded their demographic characteristics and knowledge and attitudes regarding organ donation. We then assessed the effects of informing participants about limits to their access to organ transplants on their willingness to donate.

Results

This group of 59 uninsured Hispanic immigrants had adequate knowledge about organ donation. Participants were suspicious about inequality within the medical system, but most were willing to donate their organs (74 percent). Most participants (74 percent) were aware that they would have to pay to receive an organ, but they dramatically underestimated the out-of-pocket expenses. Yet willingness to donate their organs was unaffected by participants being explicitly informed of the low likelihood that they would be able to afford to receive an organ transplant.

Conclusions

Despite being well informed about the organ donation system, undocumented Hispanic immigrants underestimate the costs and overestimate their likelihood of receiving an organ. Even when they are given this information, they remain willing to donate their own organs.

INTRODUCTION

Undocumented immigrants are able to, and do, donate their organs, but they are effectively barred from receiving organ transplants because of their legal status.[1] This challenges a fundamental principle

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of organ donation: fairness. Further, it is not known whether undocumented immigrants appreciate this inequity and, if they did, whether it might affect their decision making about donating their own organs. Not providing potential organ donors with information that might be relevant to their decision undermines another basic ethical principle of organ donation: informed consent.

These questions of fairness and access have not been a significant part of the discourse around organ donation. The conversation has predominantly focused on scarcity and methods to address the paucity of available organs for people in need. The need to increase organ donation is important, but should not come at the expense of the rights of vulnerable groups. The American Medical Association (AMA) and the Organ Procurement and Transplant Network (OPTN) have spoken to this concern. The AMA's "Principles of Medical Ethics" state that potential donors should be fully informed of the consequences of their decisions and free of coercion.[2]

OPTN Policy 6.2.1 states, "deceased donor organ allocation to candidates for transplantation shall not differ on the basis of a candidate's citizenship or residency status in the U.S."[3] Despite this, most undocumented immigrants are excluded from the organ transplantation pool on the basis of their legal status. As Goldberg and colleagues describe, current U.S. legislation makes it difficult for many undocumented immigrants to access needed transplants.[4] This lack of access is not based on the potential utility of the transplanted organ; it is based on restrictive reimbursement criteria for organ transplants. Undocumented immigrants are uninsurable through plans supported by the federal government.[5] In order to receive an organ transplant, they would need to cover all expenses independently—an exceedingly rare occurrence.[6] There are approximately 7.2 million uninsured, undocumented immigrants in the U.S.[7]

Although they are not eligible to receive organ transplants, undocumented immigrants have the capacity to donate their organs. They frequently enter the medical system through emergency and charity care systems.[8] Once they are in the system, the "required request" policies of the Joint Commission and Medicare insure that undocumented immigrants will be asked about their wishes regarding organ donation.[9] No stipulations are made regarding their lack of U.S. citizenship.[10]

Currently, this information is neither routinely nor explicitly discussed with these patients or their surrogates. Although the attitudes of minority populations such as the African-American, Hispanic, and Asian communities about organ donation have been studied, little is known about the attitudes of undocumented immigrants toward organ donation or about their knowledge of the barriers to organ transplantation. Previous studies of barriers for the Hispanic community, in particular, emphasized distrust of the medical establishment, language differences, religious issues, and concerns about mutilation of the donor's body.[11] Furthermore, little is known about whether this population would consider information about their potential to receive organs relevant to their decision to donate their own organs. To evaluate whether this information would affect their decisions to donate organs, we created a survey in which we provided a sample of undocumented immigrants with information on their limited ability to receive a transplant. We then reassessed their willingness to donate their organs.

METHODS

We conducted this study at Cook County Hospital, a 500-bed public hospital in Chicago, Illinois. Data were collected from December 2009 to September 2011. The study was approved by the hospital's institutional review board.

Eligible patients were general medicine inpatients 18 years or older who spoke English or Spanish and self-identified as undocumented immigrants or legal residents who had lived in the U.S. for less than five years. Legal residents are eligible for Illinois Medicaid after five years of residency. Patients were excluded if they reported having cancer, human immunodeficiency virus (HIV), or chronic viral hepatitis, as these are considered absolute contraindications for organ donation. We reasoned that if patients knew they would not be eligible to donate organs, they would respond to our questions differently. We also excluded patients who were incarcerated or unable to consent.

We used a convenience sample of patients admitted to the general medicine wards. Each morning, attending physician hospitalists on the general medicine service who had admitted new patients the day prior were asked if they had potentially eligible patients for study. The interviewer approached identified patients for enrollment and verbal consent. If consent for participation was obtained, patients were screened. A single interviewer (CM) performed all of the interviews at the bedside on the first hospital day.

After the initial screen, the interview consisted of one open-ended question and 32 closed-list questions. It took about 10 minutes to complete. The in-

terview was developed based on prior research[12] and our consensus opinion. The interview was pilot tested on 15 patients to ensure that the questions were comprehensible; no data from the pilot testing were used in the final analysis.

The survey consisted of three parts: (1) an assessment of knowledge, beliefs, and attitudes about organ donation; (2) an intervention in which participants were informed about the barriers to access for organ transplantation followed by a reassessment of their attitudes; and (3) a collection of demographic characteristics (see the appendix).

To determine their level of knowledge, we asked a single open-ended question about patients' understanding of organ donation and 21 closed-list questions about their exposure to information about donation. We explored beliefs about body disfigurement and beliefs about the presence of an unsanctioned or "black" market for organ transplantation, as these are areas found to be of particular concern in the Hispanic population and are predictive of willingness to donate.[13] We assessed the participants' willingness to donate their own organs and those of their loved ones, both in the U.S. and in their home country. We asked whether they had discussed end-of-life issues, and organ donation in particular, with family members and friends, as this has been found to be predictive of willingness to donate.[14]

The intervention began with an assessment of the patients' insurance status. We then asked whether they understood that, without insurance, they would be responsible for all of the costs incurred by an organ transplant. After asking them to guess how much transplantation of a heart, a liver, and a kidney cost, we gave them the actual estimated cost of each of the procedures.[15] We then reassessed their willingness to donate and asked them whether they believed this information was important. Other than their estimation of the cost of transplantation, all questions were posed in a "yes/no" format.

Statistical Analysis

We judged that, if 10 percent of the participants who had previously agreed to donate their organs decided not to donate them after the intervention, the impact would be considered meaningful. To generate an estimate with 80 percent power for the lower bound of a 90 percent confidence interval (C.I.) to exclude this meaningful impact, we estimated that we would need 60 participants.

We used descriptive statistics to summarize the relevant variables. Given the large number of participants willing to donate organs and the relative homogeneity of the overall population, we did not estimate associations between demographic variables and participants' willingness to donate organs.

Assessment of the effect of the intervention was made using McNemar's test. The McNemar's test evaluates whether proportions measured before and after an intervention in the same group are significantly different.[16] Data for this test was dichotomized into "yes" responses and "non-yes" responses. "Non-yes" responses included patients who answered "no" and those who answered "don't know." All analyses were performed with Stata 10.1.[17]

RESULTS

Of the 60 patients enrolled in the study (see figure 1), 59 completed it. The participants were predominantly uninsured Mexican immigrants with a high school education or less (see table 1). Spanish was the preferred language for every patient except one. Most had family living in the U.S. and family members who were U.S. citizens.

Table 2 provides detailed information about the participants' responses to the survey. Of the 60 participants, 39 (65 percent) had seen information about organ donation within the past year, and 53 (88 percent) did not worry that organ donation would disfigure their body. However, 31 (52 percent) believed that there is a black market for organ donation in the U.S., which suggests that participants had concerns about inequity within the medical system.

Responses to indicators of willingness to donate were mixed. Nearly three-quarters (72 percent) of participants expressed willingness to donate their organs when they die, but only 22 (37 percent) expressed willingness to donate their family members' organs when their family members die. Participants were 19 percent more likely to agree to donate organs of family members if they were living in their home country rather than in the U.S. (95 percent C.I. 5 percent to 33 percent, $p = 0.004$ for the difference). Yet this difference, based on country of residence, was not significant when referring to their own organs (absolute difference 3 percent, 95 percent C.I. -4 percent to 14 percent, $p = 0.18$).

Although rates of reported willingness to donate their organs were high, participants' rates of communication with family and friends about organ donation and death arrangements was low: 22 (37 percent) had discussed organ donation, and 17 (28 percent) had discussed death arrangements with their family.

Regarding the intervention, 74 percent knew that they would have to pay for an organ if they did not have health insurance, but, as a group, the partici-

pants dramatically underestimated the cost of transplants (see table 3). Being informed of this discrepancy between their estimated cost for transplant and the actual cost had no statistically significant impact on the group's willingness to donate organs (95 percent C.I. -8 percent to 14 percent, $p = 0.5$ for the difference) (see table 4). No patients who originally agreed to donate their organs changed their mind after learning this information. Although the information didn't affect their reported willingness to donate their organs, a large majority (49 participants, 82 percent) felt that this was information that their doctor should tell them (see table 2).

DISCUSSION

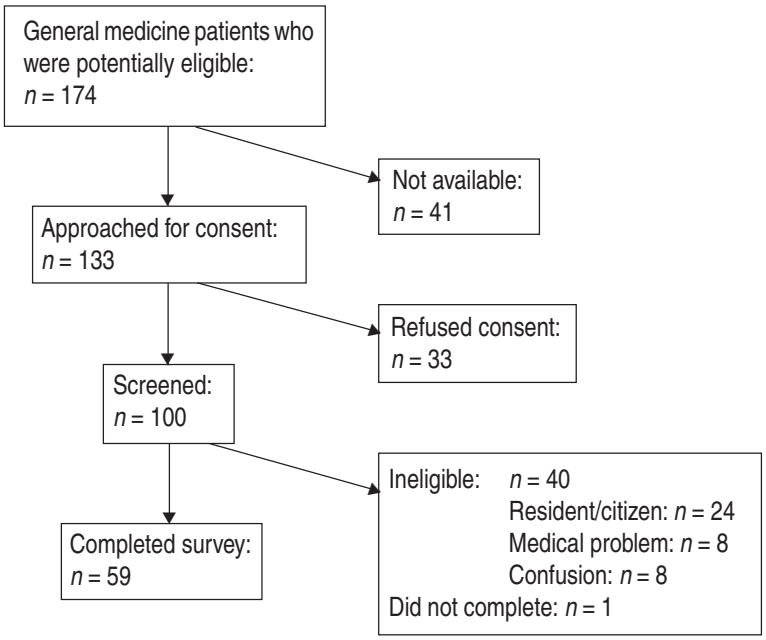
To our knowledge, this is the first study of the beliefs and attitudes of the undocumented, Hispanic, immigrant population in the U.S. about organ donation. This population is faced with unique barriers to access that might cause their attitudes about organ donation to be very different than people of similar cultural background who are legal residents in the U.S. and, consequently, insurable. We hypothesized that information about this inequity within the organ transplantation system would be relevant for potential donors from the undocumented immigrant community to make a fully informed decision regarding organ donation. This study assesses the opinions of a group of undocumented, Hispanic immigrants regarding the relevance of information about their limited access to organ transplants to their decisions about organ donation.

Our study population came from an urban, county-funded hospital. They were predominantly Mexican, and the language preference for the majority was Spanish. This language preference is a marker for limited acculturation.[18] They also had a low educational achievement status and were predominantly uninsured (93 percent). However, the cohort was relatively well informed about organ donation, particularly when compared to other studies of Hispanics. For instance, McNamara and colleagues found that only 46 percent of Hispanic citizens in their study had seen information about organ donation within the prior year, while 65 percent of our participants reported having seen information about organ donation in the prior year.[19]

Regarding our primary hypothesis, undocumented immigrants in our study clearly felt that being informed about their barriers to access to organ transplants is important. In our intervention, we gave the study participants two key pieces of information that effectively exclude them from organ transplant lists. We informed them that, if uninsured, they need to pay for organ transplant on their own, and we gave them the true cost of organ transplant procedures; 82 percent felt this was information that doctors should tell their patients who are considering organ donation. It is interesting that this knowledge did not affect their willingness to donate organs. Although our study has limitations, our data suggest that providers might have a robust conversation about organ donation with these patients, including discussion of barriers to access to organ transplantation for their community, without adversely affecting their willingness to donate.

From an ethical standpoint, the need for a robust informed consent process that includes a discussion of inequalities within the organ donation system is clear. However, this obligation for informed consent often conflicts with a countervailing desire to insure that critically ill people have access to lifesaving organs.[20] This desire to maximize the number of lives saved may cause health professionals to avoid proactively discussing unfairness within the organ donation system; our data undermine this argument. Based on our data, undocumented Hispanic

FIGURE 1. Flow diagram of patient enrollment in the study



immigrants prefer this type of high-information conversation, which suggests that there may be benefits to the relationship between health professionals and patients and families from explicit, proactive discussions of inequities within the system. Although we do not study this outcome here, one might imagine that there could be a positive effect on willingness to donate one's organs as a result of such a robust consent process.

We find this continued willingness to donate organs despite the clarification of barriers to organ transplantation surprising, although reassuring. This suggests to us that an unselfish regard for the welfare of others persists within this community. Although we certainly hope that altruism is what motivates our organ donors, to see it corroborated in this way is encouraging. However, although undocumented immigrants may autonomously choose to donate their organs despite significant limitations to their access to transplantation, this does not mean that it is acceptable to continue to propagate an unfair system that determines access to organ transplantation based on social criteria.

TABLE 1. Sociodemographic characteristics of 59 participants

	n	%
Female	33	55
Highest level of education		
Less than high school	24	40
High school	28	47
More than high school	7	12
Religion		
Roman Catholic	46	77
Other[1]	13	22
Marital status		
Married	23	38
Unmarried	19	32
Widowed	9	15
Separated	5	8
Divorced	3	5
Have children	52	87
Number of children [mean (SD)]	3	2
Family members living in the U.S.	52	87
Have family members who are U.S. citizens	38	63
Insured	4	7
Country of origin		
Mexico	54	92
Other[2]	5	8

NOTES

1. Other religions were: other Christian (*n* = 11), 7th Day Adventism (*n* = 1), and none (*n* = 1).

2. Other countries of origin were: Guatemala (*n* = 2), Chile (*n* = 1), Ecuador (*n* = 1), and Phillippines (*n* = 1).

TABLE 2. Participants' attitudes and knowledge related to organ donation

	Participants answering "yes"	
Question	*n*	%
Knowledge of organ donation		
Aware of need to self-pay if uninsured	41	68
Seen information in the past year	39	65
Known a transplant recipient	14	23
Known an organ donor	8	13
Believe organ donation disfigures body	4	7
Communication about organ donation		
Doctors should tell patients about costs of organ transplant	49	81
Discussed organ donation with family	22	37
Discussed organ donation with friends	20	33
Discussed disposition of dead body with family	17	28
Willingness to donate		
Willing to donate organs to family member	56	93
Willing to donate organs in home country	46	77
Willing to donate organs	43	72
Willing to donate family member's organs in home country	33	55
Willing to donate family member's organs	22	37
Beliefs about organ donation		
There is a black market for organ donation[1]	31	52
Important to have all body parts upon burial	12	20

NOTES

1. 12 participants (20%) answered "don't know."

TABLE 3. Participants' estimated costs for organ transplantation

	Median estimated cost, $000s (IQR)	Actual cost, $000s[1]	Difference, $000s[2]
Heart	50 (12.5 to 175)	620	570
Liver	50 (10.0 to 205)	525	475
Kidney	49 (7.5 to 135)	250	201

NOTES

1. R.H. Hauboldt, "2007 Organ and tissue transplant cost estimates," *Milliman USA,* 1 November 2007, *http://www.milliman.com/expertise/healthcare/publications/rr/pdfs/2007-US-Organ-Transplant-RR11-01-07.pdf,* accessed 2 September 2009.

2. Indicates the difference between the median estimated costs and the actual costs.

Our conclusions about altruism, despite limited access within this community, are reinforced by our finding that, whether participants imagined donating their organs in the U.S. or in their home country, they remained equally willing to be an organ donor. The relevance of this evidence is tenuous, as our study was not powered to detect what may have been a subtle difference between willingness to donate in the U.S. and in their home country. Furthermore, participants were significantly more likely to donate their family members' organs if they lived in their home country. This discrepancy between willingness to donate one's own organs and unwillingness to donate a relative's organs has been described elsewhere among Hispanics, so it is likely a cultural phenomenon that is unrelated to our participants' feelings of altruism or engagement in the community in which they live.[21] They may be less willing to donate their family members' organs in the U.S., however, because they feel more marginalized from the larger community than they do in their home country. We cannot evaluate this hypothesis with this small sample.

Our study revealed several other important insights into the undocumented Hispanic immigrant community regarding organ donation. The proportion of participants willing to donate their organs was very high (72 percent); it exceeded those from other studies of the Hispanic community and approached those for the population as a whole.[22] We can only speculate on the reasons for these discordant findings. They may reflect differences in methodology, unique attitudes among people who make sacrifices to come to this country, or a shift in beliefs in the population as a whole in the recent past. Alternatively, the findings could be explained by the fact that our group is less well informed about organ donation compared with other groups in the literature.[23] Studies indicate that Hispanics who are uninformed about organ donation are more likely to be organ donors.[24] Further work needs to be done to examine the attitudes of our population.

We also found evidence of poor communication about organ donation within our immigrant Hispanic cohort. This is not surprising, given the lack of communication within Hispanic communities about end-of-life issues that has been documented in the literature. This literature suggests that Hispanics discuss death arrangements much less frequently and are more uncomfortable with thinking about death than people of other ethnicities.[25]

Our study has several limitations, and the conclusions should be interpreted as generating hypotheses. Our sample was small and limited to a single institution. Although the numbers are small, this remains the first study of this population's attitudes about organ donation. By using a dichotomous format (yes/no), we did not assess the degree of support that undocumented immigrants give to organ donation. A 2005 Gallup Poll reports that, although people of all races support organ donation in large numbers, the degree of support (strongly support versus support) differs between races.[26] Our survey was face-to-face, not self-administered. There may have been a significant social desirability bias to participants' answers. Finally, reported willingness to donate does not correlate well with organ donation, or even key intermediate behaviors such as completing an organ donor card; so the true clinical significance of these results is unclear.[27]

These results provide insight into the beliefs and values regarding organ donation of a large community within the U.S. whom, to our knowledge, have never been formally studied. Our study empirically addresses the impact of a robust informed consent process on organ donation discussions with undocumented Hispanic immigrants. For this community, the overwhelming majority believe that information about barriers within the system is an important part of the informed consent process. Yet it does not appear to affect their decisions about whether to donate their organs or not. Expanding these conversa-

TABLE 4. Effect of intervention on participants' wishes regarding organ donation

		After intervention[1]		
		Wish to donate organs	Do not wish to donate organs or preference unknown	Total (before)
Before intervention	Wish to donate organs	40	3	43
	Do not wish to donate organs or preference unknown	5	11	16
	Total (after)	45	14	

NOTES

1. McNemar's test was performed to evaluate for an effect from the informational intervention. $p = 0.48$. The 95% confidence interval for the proportion of participants who wished to donate organs *before* the intervention but did not *after* the intervention was -8% to 14%.

APPENDIX

[Interviewer: Subjects should only be prompted with "yes" or "no." Only mark "unsure" if the subject responds with this independently.]

1. Are you a U.S. citizen?
   - ☐ (0) No
   - ☐ (1) Yes *[If "yes" then stop.]*
   - ☐ (2) Unsure
2. Are you a permanent resident?
   - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
3. If so, how long have you been a resident?
   - ☐ (0) 0-5 years ☐ (1) >5years ☐ (2) Unsure

[If greater than 5 years, then stop.]

4. What country are you from, originally?
   - ☐ (0) Mexico ☐ (1) Poland
   - ☐ (2) India ☐ (3) Pakistan
   - ☐ (4) Other:
5. Other: _____

People know and understand many different things about organ donation. Just so that I know that we're on the same page, could you briefly tell me what you know and understand about why we do organ donation and how it works?

6. Notes: _____
7. Organs identified by subject: _____

[If incorrect or "no," then tell them:]

Organ donation is the removal of healthy, internal body parts, or organs, from one person for the purpose of putting them in someone else whose organs aren't working normally. When someone gets a healthy organ put in their body to replace the organ that isn't working normally, it is called an organ transplant. Organs that can be transplanted include: kidneys, hearts, livers, lungs, intestines, and pancreas. Some organs, like kidneys, can be given by someone who is still living. Many organs are given by people that have recently died. For these people, their families often make the decision to give their organs away for them. In the U.S., it is illegal to sell organs, they are only given away for free.

8. Do you know about any medical problems you have that would exclude you from donating an organ?
   - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure

[If "yes":] What are those problems? *[Mark all that are mentioned:]*

9. Infection: ☐ (0) No ☐ (1) Yes
10. Cancer: ☐ (0) No ☐ (1) Yes
11. Cardiac: ☐ (0) No ☐ (1) Yes
12. Pulmonary: ☐ (0) No ☐ (1) Yes
13. Hepatic: ☐ (0) No ☐ (1) Yes
14. Alcohol or Drugs: ☐ (0) No ☐ (1) Yes
15. Other _____
16. *[If cancer, HIV, Hepatitis B or C—confirm type of hepatitis—then stop.]*
    - ☐ (0) Cancer ☐ (1) HIV
    - ☐ (2) Hep B ☐ (3) Hep C
    - ☐ (4) Hepatitis—type unknown
17. Other: _____

[If anything else, let them know that they may still be able to dontate an organ and proceed.]

18. *[If unsure:]* For instance, Do you have cancer?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
19. Do you have any chronic infections?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure

[If "yes" to any of the above, then stop. If "no" continue on:]

Unless I tell you otherwise, all questions can be answered with a "yes" or a "no."

20. Have you seen information about organ donation in the past year?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
21. Have you ever known anyone who donated an organ?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
22. Have you ever known anyone who received an organ?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
23. Have you ever discussed organ donation with your family?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
24. Have you ever discussed organ donation with your friends?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
25. Some people have thoughts about what they want to happen with their body after they die. Have you ever discussed what you want to happen with your body after you die with your family?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
26. Would you be willing to give your organs away when you die?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
27. If you did not know their wishes, would you be willing to give your family member's organs away when they die?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
28. Would you be willing to give an organ to your family member, if they needed it?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
29. If you lived in [home country] would you be willing to give your organs away when you die?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
30. If you lived in [home country] would you be willing to give your family member's organs away when they die?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
31. Many people worry that donating their organs would disfigure their, or their family member's, body. Is this something that worries you?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
32. Many people feel that it is important for a person's body to have all of its parts when it is buried. Is this important to you?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure
33. A black market is where things are bought and sold illegally. Some countries have black markets for organs. Do you think there's a black market for organ donation in the U.S.?
    - ☐ (0) No ☐ (1) Yes ☐ (2) Unsure

APPENDIX, *continued*

34. Do you have health insurance?
☐ (0) No ☐ (1) Yes ☐ (2) Unsure
35. People without health insurance can only get an organ transplant if they pay for it themselves. Did you know that you would have to pay for an organ yourself if you needed it?
☐ (0) No ☐ (1) Yes ☐ (2) Unsure
I would like to ask you how much you think it costs to get an organ transplant. I will ask you about 3 different organs. Please give me your best guess (in dollars) about how much the surgery would cost.
36. Heart: ☐ $ _____ ☐ (1) Don't know
37. Liver: ☐ $ _____ ☐ (1) Don't know
38. Kidney: ☐ $ _____ ☐ (1) Don't know
It actually costs about about $660,000 to get a heart, $520,000 to get a liver, and about $250,000 to get a kidney.
39. Knowing this information, would you be willing to give your organs away when you die?
☐ (0) No ☐ (1) Yes ☐ (2) Unsure
40. If you lived in *[home country]* would you be willing to give your organs away when you die?
☐ (0) No ☐ (1) Yes ☐ (2) Unsure
41. Do you think that this is information that doctors should tell their patients who are thinking about donating an organ?
☐ (0) No ☐ (1) Yes ☐ (2) Unsure
42. Sex
☐ (0) M ☐ (1) F ☐ (2) Transgender
43. How far did you go in school?
☐ (0) <High School ☐ (1) High School
☐ (2) College ☐ (3) Graduate
44. What religion were you raised in?
☐ (0) Baptist ☐ (1) Catholic
☐ (2) Other Christian ☐ (3) Muslim
☐ (4) Hindu ☐ (5) Buddhist
☐ (6) Other
45. What is your current marital status?
☐ (0) Married ☐ (1) Unmarried
☐ (2) Divorced ☐ (3) Separated
☐ (4) Widowed
46. Do you have any children? If so, how many?
☐ (0) No ☐ (1) Yes
47. If "yes," number: _____
48. Do you have any family in the U.S.?
☐ (0) No ☐ (1) Yes
49. Are your family members U.S. citizens?
☐ (0) No ☐ (1) Yes ☐ (2) Unsure
50. What is your language of preference?
☐ (0) English ☐ (1) Spanish ☐ (2) Polish
51. ☐ Other:_____
52. In the past year, how many times have you been hospitalized? ☐ (0)#: _____ ☐ (1) Unsure

tions is consistent with the goals of an ethically sound organ donation program, and ought to become standard practice.

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Ethically Informed Pragmatic Conditions for Organ Donation after Cardiocirculatory Death: Could They Assist in Policy Development?

Jeffrey Kirby

ABSTRACT

The modern practice of organ donation after cardiocirculatory death (DCD) emerged in the 1990s as a response to the alarmingly wide gap between the number of transplantable organs available through organ donation after neurological death and the urgent organ transplantation needs of persons in end-organ failure. Various important ethical dimensions of DCD have been considered and debated by prominent organ donation/transplantation theorists and clinicians.

In this article, consideration of some of these ethical elements provides a foundation for a proposed set of ethically informed, pragmatic conditions that could assist in the development of health policies to guide the practice of organ donation after cardiocirculatory death.

INTRODUCTION

Although organ donation after cardiocirculatory death (DCD) is now practiced extensively in North America and elsewhere, organ donation/transplantation (OD/T) theorists and clinicians remain engaged in a variety of debates about issues of relevance to this practice. These issues include disagreement about the interpretation of the cardiocirculatory definition of death and uncertainty about the determination of death for the purposes of DCD. Partly as a result of these differences, DCD practices vary somewhat, and the procedural policies that guide practice often pay suboptimal attention to the ethical dimensions of organ donation in this context. In this article, unresolved ethical issues and ethics-related questions of particular relevance to DCD are briefly examined. One under-explored issue concerns the "live-dead" moral distinction between the status of DCD and brain-dead donors and how this distinction impacts consent-to-donate obligations. On the basis of a consideration of these issues and questions, a set of pragmatically achievable conditions is proposed that could be potentially incorporated into healthcare policies that direct DCD practice. A key condition sets out what, in the author's view, constitutes a comprehensive informed consent process for DCD. Given that OD/T theorists, including Franklin Miller, Robert Truog, and Dan Brock, have put strong emphasis on "valid consent" as a condition for the ethical acceptability of OD/T, it is crucial to get this consent process "right."[1]

For the purposes of this article, the practice under consideration is controlled DCD, in which a very ill, but not brain dead, individual has been cared for in a critical care setting and, after withdrawal of life-sustaining treatment, there is an interval of time between cessation of cardiocirculatory function and declaration of the donor's death. Such an interval is

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not required in organ donation after neurological death, because the donor is considered to be irreversibly *factually* dead after brain death has been formally determined.

EVOLVING ORGAN DONATION PRACTICES

In the early days of organ donation and transplantation—from the 1950s to the mid-1960s—the death of a potential organ donor was determined on the basis of then-accepted cardiopulmonary criteria. Various concepts of brain death were introduced in the early to mid-1960s, and, by 1968, the neurological determination of death emerged as the standard for the purposes of OD/T, on the basis of an influential report authored by an *ad hoc* committee at Harvard Medical School that defined death as whole (integrative) brain death—that is, the irreversible loss of all functions of the brain, including cortical and brain stem functions.[2] This change in practice coincided with the emergence of the *dead-donor rule,* that states that vital organs (those necessary for sustaining life) can only be procured from dead bodies,[3] what George Khushf refers to as the first pillar of current OD/T policy.[4] The neurological determination of death continues to be perceived by relevant professional communities and the public at large as an appropriate method for determining the death of a potential donor.

Following and consistent with recommendations of the U.S. President's Council on Bioethics, the second pillar of OD/T policy—namely, the dual definition of death (death is constituted by the irreversible cessation of cardiocirculatory function or the irreversible loss of whole brain function)—emerged and was widely adopted for the purposes of OD/T.[5] The modern practice of DCD began in the 1990s, as a response to the wide disparity between the number of organs that were accessible through donation after neurological death and the number of individuals with end-organ failure who were in urgent need of a transplantable organ. According to Alister Browne, the motivation to pursue and standardize DCD was "to expand the donor pool by including in it patients who are in hopeless conditions but who are not dying because of brain injury and hence will not suffer the neurological death necessary to become heart-beating donors."[6]

SELECTED ETHICAL CONSIDERATIONS

In this section, a number of ethically related concepts and considerations of relevance to DCD are briefly explored. These concepts and considerations inform the establishment of a proposed set of conditions that could potentially assist in the development of health policies to guide DCD practice.

Social Utility

It is widely recognized by theorists that the primary ethical justification for OD/T practices is utilitarianism (a version of consequentialism), that holds that persons are obliged to decide and act so as to produce the greatest good for the greatest number. In this context, the desired important *good* is health benefit, in the form of enhanced duration and quality of life, for organ recipients. As Andrew Sneddon indicates, "the most fundamental reason to acquire organs at all is utility,"[7] while Robert Arnold and Stuart Younger speak of this motivation as the "irresistible utilitarian appeal of organ transplantation."[8] Proponents of OD/T also sometimes reference values of efficiency and "healthcare sustainability" in making the claim that OD/T results in a better health benefit "bang" for the limited health resource "buck," when compared to the therapeutic benefits and financial costs associated with alternative life-sustaining technologies such as prolonged renal dialysis.

Khushf comments that, in the context of OD/T, considerations of utility that exist around "optimizing the number of available organs" have tended to "push" death criteria to the "near side" of the dying process. And, in his view, countervailing considerations of respect (for persons) and "strong individuality concepts" have had a tendency to push criteria to the "far side" of the dying process.[9] A similar tension plays out in the current uncertainty and disagreement about how much non-interventional time is required between cessation of cardiocirculatory function after withdrawal of life-sustaining treatment (WLST) and declaration of death in the DCD context. These tensions and related competing obligations are addressed in later sections of the article.

Conflict of Interest

An ethically related consideration of theoretical and practical interest in the OD/T context is conflict of interest. A conflict of interest exists in circumstances when a person's or an organization's primary obligation is, or could be, influenced by a secondary interest. With reference to OD/T, Robert Steinbrook comments, "to avoid obvious conflicts of interest, neither the surgeon who recovers the organs nor any other personnel involved in the transplantation of the organs can participate in end-of-life care or the declaration of death."[10] Most clini-

cians recognize and acknowledge that the early participation of health practitioners on the transplantation side, whose primary goal is to meet the urgent, therapeutic needs of potential organ recipients, constitutes a legitimate conflict of interest. For this reason, it is a widely accepted, modern practice in North America to separate (clinical and patient/family) decision making about WLST from subsequent approaches to substitute decision makers about potential organ donation. Unlike some of the other ethical elements of OD/T, this conflict of interest consideration (and its effective management) is one aspect of OD/T practice that is importantly guided by a relatively straightforward and accessible ethical and health law concept.

Concerns about Transparency and Openness

There is limited comment and critique in the literature regarding the less-than-optimal transparency about what OD/T actually entails.[11] Quite understandably, educational and promotional efforts aimed at members of the public typically focus on the concrete benefits of OD/T to individuals with urgent health needs (and, to a lesser extent, donor families), and tend to be rather "light" on the specific details of OD/T practices. This may be due to a belief that fewer individuals will express an interest in donating their organs if they are fully informed about OD/T procedures. A review of the literature failed to reveal existing empirical support for a claim that enhanced transparency about OD/T procedures leads to a reduction in the rate of organ donation. Current practice around disclosure to members of the public about OD/T could also be influenced by a belief among healthcare providers (HCPs) that disclosure does not need to be highly detailed when decisions are being made about the disposition of dead bodies.

Another factor that could contribute to a lack of transparency the a concern that it may not be in the best interest of members of the public and HCPs to become aware of the complex philosophical debates and disagreements about death criteria and the status of potential donors at the time of organ procurement. James DuBois has commented that significant harms can result from fostering doubts about these matters, which may include the generation of unnecessary distress and a possible reduction in the rates of organ donation.[12] Although these projected burdens seem possible, they do not provide clear rationales or justifications for less-than-full transparency about the nature of OD/T procedures, including the use of pre-mortem investigations and interventions in DCD practice.

Disagreement about Interpretation of the Cardiocirculatory Definition of Death

Disagreement about interpretation of the cardiocirculatory component of the previously described dual definition of death has been recently addressed in the literature by prominent OD/T theorists and clinicians.

One primary focus of debate relates to the importance and meaning of the descriptor *irreversible* in the definition of death. In scientific and ordinary usage, to have the property of *irreversibility* means that the condition under consideration can never be reversed.[13] Applying this interpretation to the DCD context, *irreversible* cessation of cardiocirculatory function exists when a person's cardiocirculatory function cannot be reversed under any circumstances. However, such an interpretation is inconsistent with the way death is determined in current DCD practice because, after the passage of a usually rather short period of time (for example, two to five minutes) between cessation of cardiocirculatory function after WLST and the declaration of death, autoresuscitation (spontaneous return of cardiocirculatory function after assumed clinical death) is at least theoretically possible. It is also conceivable that cardiopulmonary resuscitation efforts, if attempted, could restart the heart and circulation.

Current scientific research to support the frequency of autoresuscitation after assumed death is weak.[14] James Kirkpatrick and colleagues comment that "existing empirical data cannot confirm or disprove a specific interval at which the cessation of cardiopulmonary function becomes irreversible."[15] With specific reference to DCD practice, the longest reported interval between cardiac arrest and autoresuscitation has been about one minute (as of 2010).[16]

Some proponents of DCD contend that an acceptable interpretation of the definition of death for DCD purposes is that the cessation of cardiocirculatory function following WLST is permanent in a normative sense, that is, cardiocirculatory function cannot be restored due the obligation of HCPs to respect existing ethical and health law norms. This is because, in most countries, cardiocirculatory function cannot be restored after a decision has been made through a process of informed consent to permanently withdraw life support. James Bernat considers this sense of normative permanence to be a valid surrogate for *irreversibility* in the DCD context.[17] Don Marquis argues against this claim in support of his contention that "DCD donors are not known to be dead," that is, without neurological determination of death, sufficient conditions (includ-

ing physiologically permanent *irreversibility* of cessation of cardiocirculatory function) for declaration of death are not met.[18]

For the purposes of this article and its focus on ethically informed pragmatic conditions for DCD, a normative interpretation of the cardiocirculatory definition of death seems adequate, given that the context under consideration is a practical, clinical one in which norms regarding health law and ethics guide the decision making of affected parties. However, the question of whether the donor is *dead* on the basis of permanent irreversibility of cardiocirculatory function at the time of organ procurement remains important and relevant in discourses about health policy, which rightly questions whether existing DCD policy should be modified—up to and including the potential discontinuation of this OD/T practice. That being said, in a modern world of rapidly emerging, highly technical health interventions in which the balancing of competing ethics obligations is often only attempted retrospectively, arguments in favor of discontinuing existing DCD practice on the basis of irreversibility and/or other theoretical considerations will have to be both strong and understandable to the general public if they are to be effective in countering the perceived obligations of HCPs and society as a whole to meet more of the urgent needs of persons in end-organ failure than can be met with the exclusive use of a neurological definition of death.

Uncertainty about the Determination of Death

In the past decade, some theorists have challenged the scientific validity of the neurological determination of death and the utility of the dead-donor rule. It is now known that some persons who meet the criteria for neurological determination of death continue to perform a variety of complex, integrative biological functions including metabolism, hormonal balance, infection control, and fetal gestation. Because of this, Miller, Truog, and Brock consider brain death to be a "moral fiction," that is, a false belief motivated by considerations of utility regarding OD/T.[19]

With reference to the determination of death for pragmatic DCD purposes, there is uncertainty in the literature about what is an acceptable time interval between cessation of cardiocirculatory function following WLST and the declaration of death. Internationally, there exists considerable variability among DCD practices in the specified amount of minimally required time (from 75 seconds to 20 minutes[20]). The motivation for keeping this time interval short is a practical one: the longer that potentially transplantable organs have less than optimal blood supply between WLST and transplantation, including the interval when there is no blood supply between cessation of cardiocirculatory function and the declaration of death, the greater the chance that functional viability of the organs will be compromised.[21] However, despite the validity of this rationale for keeping the time interval short, enough time needs to elapse between cessation of cardiocirculatory function and the declaration of death for the potential donor to be considered *factually* dead by HCPs and the public (see the subsequent section).

"Live-Dead" Distinction between the Statuses of DCD and Brain-Dead Donors

An under-explored philosophical issue of particular relevance to consent-to-donate obligations is the lack of awareness and clarity about the implications of the "live-dead" moral distinction between the statuses of potential DCD and brain-dead donors. From an ethical perspective, there is a significant difference in the statuses of these two types of donors after a decision has been made to withdraw life-sustaining treatment. In DCD circumstances, the person from whom organs are to be procured is not brain dead, that is, the person does not meet the criteria for neurological determination of death in the time interval between the making of a decision to WLST and the declaration of death. Therefore, during this time frame, pre-mortem OD/T-optimizing investigations and interventions to determine and preserve organ viability are happening to a live person. There is a widely accepted, Kantian-derived proscription against treating a person "as merely a means to an end." This applies, in the context of DCD, to the use of pre-mortem investigations and interventions that are intended to determine/preserve organ viability but do not provide any therapeutic benefits to the still-living, potential donor. In these circumstances (as opposed to donation after neurological death), it could be argued, on a theoretical level, that the potential donor is being used as merely a means to the recipient-benefit ends of organ transplantation.

The reader may be wondering how various Kantian considerations that inform and constrain how persons are to be treated are of relevance to the formulation of ethically informed pragmatic conditions for the practice of DCD. Existing societal norms based in ethics and health law require that Kantian obligations of *respect for persons*—which are primarily instantiated in healthcare through the provision of support for the individual autonomy of patients—must be met by HCPs. That is, capable pa-

tients and substitute decision makers must be fully informed regarding, and make conscious choices about, the potential use of medical treatments and interventions. Such widely accepted consent obligations are considered weaker by some when the proposed actions and procedures are to be performed on dead bodies.[22] Consistent with this difference, in my view, a higher moral and legal standard of informed choice is needed for DCD (in which a living person is undergoing investigations and interventions between the decision to WLST and the declaration of death) than for organ donation after neurological death, in which such investigations and interventions are happening to an irreversibly, *factually* dead body. This distinction informs some of the content of a proposed optimally informed consent process for DCD described in Condition D of the subsequent section.

DCD proponents could make the claim that any potential harms accruing to a living potential donor from nonbeneficial investigations and interventions are at least partially offset by the furthering of the potential donor's autonomous decision to donate his or her organs. However, such a choice by a capable person must be reasonably informed. The affirmative signing of a donor declaration indicates a general preference by the signer to donate his or her own organs after he or she has died. For reasons described earlier, there is typically no reference in such donor declarations or in the content of OD/T public education/promotion initiatives to the non-therapeutic investigations and interventions that happen to the living donor prior to the declaration of death in DCD circumstances. Given this, a potential donor's wishes about the use of pre-mortem investigations and interventions in this context are typically unknown to the substitute decision maker. Health law scholars Jocelyn Downie, Chantelle Rajotte, and Alison Shea comment that "consent to pre-mortem transplantation optimizing interventions cannot be considered implied by [general] consent to organ donation."[23] Joseph Verheijde and colleagues argue that "allowing temporary organ-preservation interventions without expressed consent is inherently a violation of the principle of respect for a person's autonomy."[24]

PROPOSED ETHICALLY INFORMED PRAGMATIC CONDITIONS

Prior to the availability of sophisticated life-sustaining technologies in the mid to late 1900s, the determination of a patient's death by his or her attending physician through (then) standard medical practice was not usually questioned by HCPs or members of the public. As a result of medical and legislative support for the neurological determination of death and the partial success of promoting OD/T practices, the public has come to accept that brain death *is* death, despite the discordant presence of a warm body and beating heart from the declaration of neurological death until organ procurement. To date, despite the forceful, radical critiques of Dick Teresi,[25] theoretical debates about whether a potential donor, who is declared brain dead, is irreversibly factually dead have not significantly affected the attitudes of the general public about OD/T, nor become a conscious, overriding concern for HCPs who are actively engaged in OD/T practices. As such, there continues to be broad public and health professional support for the neurological determination of death.[26]

As a result of the recognized potential for DCD practice to narrow the critical gap between the supply of and demand for scarce transplantable organs, it seems unlikely that this well-established OD/T practice will be abandoned in the future, despite ongoing theoretical debate and disagreement about such issues as "the reversibility objection."[27] Given this, perhaps attention should be paid to the answering of a practical, ethically related question, that is, given current theoretical and clinical understandings of the practice, what pragmatic conditions would make it ethically acceptable to procure organs through DCD? In my view, an adequate response to this question is constituted by:

1. A normative interpretation and understanding of the definition of cardiocirculatory death,
2. A mechanism for determining cardiocirculatory death that is acceptable to the public and HCPs, and
3. An optimal consent-to-donate process.

With this in mind, the following set of ethically informed pragmatic conditions is proposed.

Condition A: Cessation of Cardiocirculatory Function Is Normatively Permanent

For this condition to be met, restoration of the potential donor's cardiocirculatory function by HCPs is not possible due to existing ethical and health law norms. In order for this to be so, an informed decision to permanently withdraw a potential donor's life-sustaining treatment has to be made independent of, and prior to, discussion of possible DCD with the substitute decision maker. The consent process element of relevance to this condition is described in Element 1 of Condition D.

Condition B: The Donor Is Recognized by the Public and Careproviders as Dead

For this condition to be met, enough time needs to elapse between the observed cessation of the donor's cardiocirculatory function and the declaration of death for the status of the donor's body to be recognized by HCPs and members of the public as dead, in the commonly appreciated sense of the word/concept. Educated and media-aware members of the public recognize that an individual's brain is profoundly damaged and no longer capable of meaningful consciousness after about five minutes of not receiving oxygen through spontaneous or artificial blood circulation (in the absence of significant cooling). Given this awareness and the widespread acceptance of the status of brain death as *factual* death, it is likely that many observers, including family members and HCPs, would consider the donor to be dead when his or her body has existed in a noncirculatory state for about this period of time.

Condition C: The Chance of Autoresuscitation Is Exceedingly Remote

For this condition to be met, there needs to be an adequate interval of time between cessation of the donor's cardiocirculatory function and organ procurement to make the chance of autoresuscitation (spontaneous return of cardiocirculatory function after assumed death) "vanishingly small."[28] Although empirical data to confirm the accuracy of such an interval is currently lacking, it seems reasonable to consider this interval to be five minutes, based on the previously described, limited clinical experiential knowledge. At least for the time being, this time interval has the advantage of endorsement by the U.S. Institute of Medicine.[29] Establishing a minimal interval of this duration would allow for organ procurement to proceed without prior, significant compromise of organ function due to lack of oxygenated blood supply. Although the appropriate minimal interval of time may vary on the basis of future research findings, there is no need for Condition C (itself) to be modified.

Condition D: The Consent Process Is Comprehensive and Optimally Informed

The following is a description of four elements of what the author considers to be an "as *right* as possible" consent process for DCD. Some of these elements contain components of existing DCD practices and are included here to emphasize and reinforce the longitudinal, comprehensive nature of an optionally informed consent process in this context. For the purposes of this account, it is assumed that the potential donor lacks the necessary capacity to make in-the-moment decisions regarding DCD, as these are the usual clinical circumstances in which controlled DCD is currently actualized in critical care settings. For Condition D to be met, the clinician or clinicians who provide critical care to the potential donor engage in dialogue with the patient's legitimate substitute decision maker (SDM) and ensure that the requirements of all four of the following consent elements have been achieved.

Element 1. Informed Consent for Withdrawal of Life-Sustaining Treatment

The SDM is ethically obliged to make decisions about the maintenance or discontinuation of life-sustaining treatment(s) and intervention(s) in accordance with the known, previously expressed, clear wishes of the capable person (or, in some jurisdictions when these are unknown, in accordance with the known values and beliefs of the patient). When the patient's wishes (and, in some jurisdictions, values and beliefs) are unknown, the SDM is obliged to make these decisions in accordance with what he or she believes to be in the broadly defined best interests of the patient. The timing of this first element of the DCD consent process is crucial—given the previously described potential for conflicts of interest, it must occur before the patient's SDM is approached about the possibility of DCD, that is, it has to occur independently of a subsequent decision to donate organs after cardiocirculatory death.

Element 2. Direct, General Consent to Organ Donation

In the critical care setting, an HCP or HCPs, in possible collaboration with an OD/T coordinator, determine whether the patient has given prior general, affirmative consent to organ donation. This is provided by either a written statement (for example, a donor declaration of a variety of potential sorts) or reliable information provided by another person (for example, a family member) of the patient's prior verbal expression, made while capable, of a clear wish to donate organs at the time of death. This consent element is of importance to DCD because, as described earlier, the details of this particular OD/T practice are essentially unknown to the public, and, as opposed to organ donation after neurological death, DCD involves the performing of pre-mortem investigations and interventions on a living person.

Element 3. Informed Consent for DCD

In relevant critical care circumstances, the SDM is approached about the possibility of DCD after a

decision has been made to withdraw the patient's life-sustaining treatment. In order for the SDM's decision to be reasonably informed, he or she needs to be made aware of the specifics of the DCD practice under consideration, and, in particular, the process/mechanism to be used to determine the patient's death. In the critical care setting, the disclosure of such information is performed by an HCP, in possible collaboration with an OD/T coordinator.

Element 4. Separate Consent for Pre-Mortem Investigations and Interventions

Given the general public's lack of knowledge about the specifics of DCD and the moral relevance of the "live" status of the potential donor from the decision to WLST to the declaration of death in DCD circumstances, separate consent is obtained for the use of pre-mortem investigations and interventions to determine and preserve the viability of the potential donor's organs. In order for the SDM to make an informed decision on behalf of the potential donor, descriptions of the investigations to be used to determine organ viability and the interventions to be utilized to preserve organ viability are provided to the SDM in understandable language. If some of the proposed pre-mortem interventions are not considered necessary for DCD to proceed and/or some are not required for the donation of a chosen, limited set of transplantable organs, the SDM should be informed of his or her option to not provide consent for the use of all the proposed pre-mortem interventions.

SUMMARY COMMENTS REGARDING THE FOUR PROPOSED CONDITIONS

Conditions A to D, as described above, are proposed as a set of ethically informed, pragmatic conditions for potential incorporation into policies that guide DCD practice. Rather than being of a fixed nature, the content of these conditions is designed to be contingent on current clinical evidence and theoretical understandings, and, as such, the conditions are open to iterative revision and enhancement on the basis of new clinical and theoretical developments.

Adoption of the above conditions should not be overly burdensome. The consent process might be slightly lengthened in some circumstances when there is additional discussion about the potential donor's verbally expressed wishes (in the absence of a signed donor certificate) and/or enhanced disclosure to the SDM about the use of pre-mortem investigations and interventions. Although it is possible that some SDMs will not provide consent to donate their family member's organs on the sole basis of enhanced transparency about the DCD process, there is no empirical evidence to support the prediction of an associated decrease in the rate of organ donation on this basis. If a slight reduction in the number of available, transplantable organs is experienced after adoption of these conditions, this might, in my view, be offset by the benefits of enhanced reassurance of the public and health professionals that the ethical dimensions of this relatively new OD/T practice have received appropriate attention. Such reassurance could potentially generalize to improved public confidence in the ethical integrity of all OD/T practices.

CONCLUSION

Ethical issues and questions of relevance to DCD were briefly explored in this article. Consideration of these provided the foundation for the development of a set of ethically informed pragmatic conditions, the adoption of which could help guide DCD practice. Although interesting and important theoretical disagreements are likely to persist indefinitely in the domain of OD/T, the adoption of ethically informed conditions, the content of which is contingent on current clinical and theoretical knowledge, could potentially assist clinicians "to continue to muddle through" in a "practically unavoidable or even desirable" manner.[30]

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Commentary

Why We Should Continue to Worry about the Therapeutic Misconception

Larry R. Churchill, Nancy M.P. King, and Gail E. Henderson

ABSTRACT

In a recent article in *The Journal of Clinical Ethics,* David Wendler argues that worries about the therapeutic misconception (TM) are not only misconceived, but detract from the larger agenda of a proper informed consent for subjects involved in clinical research.[1] By contrast, we argue that Wendler mischaracterizes those who support TM research, and that his arguments are fragmentary, often illogical, and neglect a critical difference between clinical care and clinical research. A clear explanation about the chief aim of research is, in fact, what gives the other elements in a consent process their meaning. We argue that informed consent must be both trial-specific and context-sensitive, and that concern about the TM is needed now more than ever.

CAN WE RELAX ABOUT THE TM? INTERROGATING THE ARGUMENTS

David Wendler has argued recently that concerns about the therapeutic misconception are misguided, overblown, not applicable in many instances of clinical research, and actually counterproductive, in that they divert attention away from the "essential elements of informed consent."[2] His effort to make good on these assertions fails, we will argue, because his analysis is fragmentary and in places illogical, and most importantly because he neglects a critical feature that distinguishes clinical care from clinical research. Not only should we continue to worry about the TM, but the case for continued vigilance on the part of investigators, institutional review boards (IRBs), and research sponsors is compelling.

One of Wendler's central claims is that the empirical work on the TM and its prevalence is based on "mistaken methods for determining what things research subjects should understand," because these studies largely assume that all research subjects need to understand the same differences between research and routine care.[3] His position is that not all patient-subjects need to understand that research and treatment are not the same thing; he proposes that the need for such understanding is context dependent, what he terms "task-specific."[4]

We might all concede some version of this. For example, understanding the essential differences be-

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tween research and treatment can be far more important in Phase I trials than in Phase III trials. But Wendler's critique is more radical. He asserts that there often is little or no "fundamental or enduring difference" between research and treatment, and that to insist that there is a difference, and to focus on efforts to communicate it, "distorts what subjects should understand."[5] He also cites the potential for "commentators to exaggerate" the differences, as, for example, when a given research protocol is arguably less risky than a standard treatment using unproven methods, because, he asserts, commentators feel the need "to identify some way in which most (or all) research studies differ from clinical care."[6]

Of course, Wendler is correct that exaggeration is possible, in the consent form, the consent process, and scholarly discussion. Furthermore, it is clear that researchers have obligations to subjects in research, as Carl Coleman has argued.[7] Yet the framework of understanding that establishes how a researcher and a subject interact is fundamentally different from the framing assumptions of doctor-patient relationships. We address this difference in relationships in the next section.

Wendler does not address this relational difference at all. Instead he claims that empirical studies and conceptual analyses of the TM to date have focused on two sorts of differences: differences in methods and differences in purposes. With regard to methods, he points to practices of randomization, double-blinding, fixed treatments, and other features often necessary in investigations that aim for generalizable knowledge. Yet these features of research methods, Wendler contends, are mostly relevant to the extent that they alter the balance of risks of harm and potential benefits, and that otherwise these differences in methods between research and clinical care may be irrelevant to valid consent. He concludes that the best remedy when there is an increase in risk is simply to state this detail, without what he considers the more difficult task of explaining the relevant differences between research and clinical care, despite the fact that this is why the differences exist. "Many potential subjects will be able to understand this [extra blood draws of no direct benefit to the subject] without having to understand that clinical research is designed to collect generalizable knowledge and that the blood draws provide a way for investigators to do so."[8] Here Wendler's argument is difficult to follow, since an adequate explanation to subjects of the need for extra blood draws would entail an explanation that they are necessary to fulfill the larger aims of research and are not needed for this patient's care. Wendler summarizes his view on methods by saying that "TM will be useful only when . . . explaining general differences in methods is useful for helping potential subjects to understand the essential elements of consent."[9] This conclusion only makes sense if we assume that knowing whether an intervention is research or clinical care is not always essential.

When Wendler turns from differences in methods to differences in purpose, the argument becomes even more strained. Here, as with the examination of methods, he stresses that too much emphasis on "the *defining purpose of research*" as the search for generalizable knowledge can lead us in the wrong direction. He rightly states that much clinical research does aim to benefit those enrolled in research, but he fails to note that this is necessarily a secondary aim, a felicitous by-product of the major research purpose, and not the chief agenda. Along the same lines, he also appears to equate the investigator's intent to benefit patient-subjects with the certainty of a beneficial effect.[10] Moreover, he seems to consider the investigator's duty to protect subjects through risk minimization, which is a requirement of all clinical trials governed by the "Common Rule,"[11] as evidence that the investigator is behaving as a clinician, thus somehow blurring the research-treatment distinction.[12]

Wendler rightly suggests that a great deal of commercially based research is aimed at profit, but here he seems to confuse the larger aims of the sponsors of the research with the primary purpose of research as discussed between investigators and research participants. Investigators can of course also be motivated by profit, as well as fame, tenure, and a range of other things. But surely listing the multiplicity of purposes of the various actors in the research enterprise is beside the point. Indeed, in his portrayal of differences in purpose, Wendler argues that understanding the large purposes of organizations and activities is often unimportant to legitimate participation. He cites as examples (1) consent to help with a car wash for charity, and questions whether in volunteering for car washing one really understands the larger aims of that charity; and (2) his own case of working for the U.S. federal government and how well he understands governmental aims.[13] The first example trivializes his case; there is usually little or no moral burden assumed by either party in a car wash. The second example seems to obfuscate the primary purpose of clinical research by suggesting it is similar to the many and varied purposes of the federal government. If we pursue this analogy, it leads in a direction that undercuts Wendler's claim.[14]

The existence of multiple and often conflicting aims among the actors in research is commonplace, and certainly is the reason for a range of disclosure requirements and conflict-of-interest management plans. What Wendler overlooks is that research has for a very long time been sanctioned and endorsed—whatever the mixed motivations of particular actors—as the pursuit of socially valuable, generalizable knowledge. This understanding is not only its definition in the federal "Common Rule," but a definition with wide professional and social acceptance. We can think of no quicker way to undermine public support for medical research than to suggest that whether or not research subjects are clearly informed that they are involved in research is somehow unimportant. This is, of course, not the only thing important to a valid informed consent, but it is hard to see how understanding the other key elements would be intelligible unless subjects were clear on the central difference of purpose, which then provides context for all the particulars that need to be disclosed. Wendler suggests that a preoccupation with the TM will dislodge other important features of a research enrollment discussion, such as disclosures of the risks of harm and potential benefits. It seems far more likely that an overall effort to eliminate or reduce the TM will lead naturally to a more accurate disclosure of the essential elements as applicable to the research study under consideration, such as risk/benefit expectations, inconvenience, randomization, and the rest.

THE CRITICAL FEATURE OVERLOOKED

Most people do not begin their interaction with healthcare professionals with a critical, structural analysis of the purposes, far less the methods, that justify the interventions they will undergo. Indeed, these things are all mediated through an important, prior feature of the activity, established at the beginning, namely, the relationship, including assumptions about what that relationship is or should be like. The TM involves a misunderstanding of purposes and methods only because it is first a misunderstanding of relationships, of the kind of relationship in which the health professional and the other party are engaged.[15] One obvious but important clue to the character of the relationships is that we typically use different names for the actors—physician or investigator, and patient or subject. So in its most obvious form, the TM is when I think I am a patient in a therapeutic alliance with a doctor, but in fact I am in a research protocol in which the physician may in fact be a doctor, may even be "my doctor," but is not acting primarily as a doctor, or my doctor, in the current set of interactions. And of course here, "not acting primarily as a doctor" means that there is a different primary purpose for at least some of the interventions at hand. There are a variety of reasons why this happens, some obvious and some more subtle. As most commentators have noted, and Dresser has written about in great detail, research is susceptible to being misunderstood as routine clinical care because the context of the clinic—white coats, doctors and nurses with name badges, sometimes a previous relationship, et cetera—looks and smells therapeutic.[16] The idea that the people I am relating to in a clinic or hospital setting are all here to help me, that they have my welfare primarily in mind, is the default assumption of our relationships with doctors and nurses. In research this assumption is false; this is the central phenomenon of the TM. Without this, misunderstandings of methods and purposes would not arise, or would be far less frequent. It is precisely this linchpin differentiation about the qualitatively divergent kinds of relationships in research and clinical care that is overlooked in Wendler's essay, and which seems to blind him to just how serious misunderstandings of purpose and methods can be.

Yet whether the TM on the part of the research subject always has adverse consequences for the subject's ongoing decision making during research participation is not the point. Even in this age of high autonomy, relationships between physicians and patients depend upon trust, and the interaction is necessarily a fiduciary one. As patients we are often comfortable with much that is left unsaid about procedures and interventions, precisely because we are secure in an understanding that our benefit is the primary professional motivation. Research interactions require a great deal more in terms of negotiation and consent precisely because this core fiduciary value cannot be taken for granted. That our trust in physicians may at times be misplaced—perhaps because of the parallel influences on the treatment relationship that arise from the larger context of healthcare delivery that Wendler discusses only in reference to research—does not alter the need to attend most carefully to the research relationship.

MORE WORRIES: THE TM AS CHARACTERISTIC OF RESEARCHERS AS WELL AS PATIENT-SUBJECTS

Everything we have said here takes on a deeper importance when we factor in the reality that it isn't patient-subjects alone who are susceptible to the TM,

but also investigators, the media, the general public, and the institutions and organizations that oversee and sponsor research as well.[17] Wendler is correct that most of the scholarly literature on the TM focuses on the perceptions and beliefs of subjects and potential subjects. Yet there is considerable evidence that physicians not infrequently refer patients to trials with the intent and expectation that a trial is the best treatment.[18] IRBs around the world approve trials in order to have something to offer patients for whom all else has failed,[19] and study sponsors and disease advocacy organizations often express the same concerns.[20] There is, moreover, ample evidence that consent forms, when not using treatment language almost exclusively, at best use conflicting and confusing terminology that conveys decidedly mixed messages to potential subjects.[21] This terminological confusion is rarely avoided well by investigators (though there are notable exceptions), and rarely corrected well by IRBs (again with some notable exceptions). Perhaps more important, in a multi-method study of consent forms and the consent process in early phase gene transfer research, we found that when investigators took seriously the limited potential for direct benefit described in their consent forms, and mirrored that in the consent process and in their own understanding, subjects were least likely to express the TM.[22]

Addressing the problem of the TM among investigators and others is especially important because it has ramifications far beyond those of the TM in research subjects and potential subjects. It is worthy of note that the definition of research in the "Common Rule" is not among the basic elements of consent that must be included in the consent form. Instead, it appears in the regulations for the benefit of investigators and IRBs, so that they can better understand the tasks before them. The first two items on the seven-item list of what makes clinical research ethical are validity and value, which together are critical for the production of generalizable knowledge.[23] The failure to conduct research according to its primary purpose is just as likely to lead to bending of inclusion/exclusion criteria, protocol deviations, and other serious compromises of data when those problems arise from a focus on benefiting patient-subjects as when they arise from the pressure to publish positive results to increase the sponsor's profits. Yet because benefiting patients who are subjects seems virtuous, the risks of harm arising from the TM on the part of investigators may be far less visible, and thus potentially more damaging.

If nothing else, attending to the TM serves as an important tool of critical self-reflection for the physician-investigator.[24] There are few substitutes for the value of a thoughtful consent process, for the purposes of information sharing, decision making, and relationship building in clinical research as well as in patient care.

THE CONSENSUS AND THE WORK THAT NEEDS TO BE DONE

Following from Appelbaum and colleagues' first empirical documentation of the TM in 1982, there have been subsequent attempts to develop scales for the TM[25] or measures of informed consent more broadly[26] that might be used to document misunderstandings and as educational tools during the enrolling of research subjects. In response, many concerns have been raised about what was being measured. Were TM researchers trying to eradicate hope, which no one should want to do? Were they confusing fundamental misconceptions of the research enterprise with less troubling mis-estimations of the potential for direct medical benefit, and how much should we care about the latter?[27]

Because efforts to measure the TM inevitably raise thorny definitional debates, we convened an interdisciplinary group of clinical investigators, social science researchers, and bioethicists to develop both an agreed-upon definition of TM and a road map for empirical measurement. This is set out in our 2007 publication, which defines the TM as existing when "individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge, regardless of whether the subjects enrolled in the trial may potentially benefit from the intervention under study or from other aspects of the clinical trial."[28] It is this definition that Wendler finds so troubling and that we defend in this rebuttal. Equally important, however, are the more specific recommendations we set forth in this consensus report, which we identify as the logical extensions of this definition and propose as guides for assessing what potential patient-subjects should understand. These six dimensions include assessing understanding of the scientific purpose; the procedures; the inherent uncertainty (clinical equipoise) regarding safety and efficacy of the intervention under study; the fact that studies typically adhere to protocols; and that, in a clinical trial setting, clinicians who are investigators are, in this setting, investigating the safety and efficacy of an intervention. We further argue that while these dimensions should be applicable across populations and studies, assessments of the TM "should be tailored to the experiences of particular groups . . . [and to pa-

tient-subjects] participating in trials with different designs."[29]

There is an ever-present tension between developing scales or measures that are universally applicable and also relevant to the particulars of individual trial contexts. There are also robust and legitimate critiques of measurement approaches that have been suggested in the literature for both misconception and misestimation. Most noteworthy is a recent publication by Weinfurt and colleagues, who (reasonably) argue that estimation of benefit in early phase oncology trials depends upon the way the question is asked. They compare benefit assessment using two different approaches ("How confident are you that the experimental therapy will control your cancer?" versus "If 100 people were to participate in this study, how many could be expected to have their cancer controlled as a result of the experimental therapy?").[30] While the "belief" type question elicits a higher mean expectation of benefit than the "frequency" type, leading the authors to recommend frequency type questions to assess subjects' expectations, the study still demonstrates significant therapeutic mis-estimation, even when the frequency question is used. Methodological challenges in empirical assessment of the TM present exciting opportunities to improve its measurement and that of research understanding generally. They do not imply, however, that the fundamental task is not worth attempting.

CONCLUSION

In his portrayal of the researchers and scholars whose work addresses the TM, Wendler offers up for critique a straw man. The approach adopted by researchers who have studied the TM does not "effectively ignore" the idea that what potential subjects should understand "depends on the study in question and the circumstances of potential subjects in that study."[31] Rather, these researchers simply disagree with Wendler when he asserts that making the research/treatment distinction is not a crucial feature of consent. Wendler calls his own approach "task-specific." Of course consent should be quite "trial-specific" regarding risks, benefits, and aspects of the protocol that would diverge from ordinary clinical care. What Wendler overlooks is that consent is also highly sensitive to context, and must account for circumstantial features of the interaction with potential subjects. One of the most important circumstantial features of enrolling most patient-subjects is that they can easily think that treatment is the primary aim of the interventions. With this in mind, it is hard to see why a trial-specific, context-sensitive discussion of the different primary aims of research and treatment could be unimportant. Indeed, just how potential subjects might the weigh risks and benefits and understand the requirements of a protocol depends on what they think the larger agenda is. We have heard many stories—most investigators can tell them—about how patients who are potential research subjects brush aside the need for a full consent process with responses that beg for a research/treatment discussion: "I'm sure you wouldn't be offering this if it wasn't good for me." Or "I have always received excellent care here, so I trust you to do what you think I need." This is common fare for research done in clinics and medical centers. In addition to a "trial-specific" consent process, we also need a context sensitive consent process, in which the possibility of the TM is always a part of the investigator's awareness.

In contrast to what Wendler seems to assume, this mindfulness does not at all require a consent process that attempts to elicit, or a consent monitoring process that would test, potential subjects' understanding of the definition of research or the conceptual foundations of the TM. He implies that the scholars engaged in TM research would require similarly unwieldy and abstract disclosures; instead, we maintain that those interested in the TM would much prefer to endorse a process designed to assist potential subjects in understanding the research study they are considering joining and what will happen to them if they do.[32] Especially in the current climate of increased attention to research, including not only pressures to produce generalizable knowledge but also pressures for medical progress and early access to innovations,[33] as well as the development of new models like "learning healthcare systems,"[34] we believe that it is possible and highly desirable both to continue thinking productively about how to recognize and minimize the TM, and how best to educate and inform patients who are also research subjects.

NOTES

1. D. Wendler, "Time to Stop Worrying about the Therapeutic Misconception," *The Journal of Clinical Ethics* 23, no. 3 (Fall 2012): 272-89.

2. Ibid. Wendler indicates what he means by the "essential elements of informed consent" on page 275, and it includes four elements, the first of which is "that enrollment involves participation in research." We argue later in this essay that it is hard to imagine fulfilling the requirement of this first element of consent without disclosing that research is, by definition, driven by the pursuit of

generalizable knowledge.

3. Ibid., 273.

4. Ibid.

5. Ibid.

6. Ibid.

7. C. Coleman, "Duties to Subjects in Clinical Research," *Vanderbilt Law Review* 58 (2005): 387-449.

8. See note 1 above, p. 277.

9. Ibid.

10. On page 278 Wendler says, "Investigators often enroll individuals in research with the intent of providing them with clinical benefit, even in Phase I studies." He makes this assertion despite the voluminous literature pointing out the uncertainty of benefit in early phase research, and despite the possibility that the investigator who wishes to benefit subjects may also be exhibiting the TM, as we will argue below. See note 1 above.

11. See 45 *CFR* 46.111(a) (1).

12. See note 1 above, p. 278.

13. Ibid., 279.

14. Assuming that federal employees have a contract for services that will sustain or further some governmental aims, and that these aims would have to be specified before employment in order to legitimate the contract, this seems quite similar to volunteering for medical research. In both cases, learning that the guiding purpose of the activity in which one is engaged has not been disclosed would be a serious breach.

15. See L. Churchill, "Physician-Investigator/Patient-Subject: Exploring the Logic and the Tension," *Journal of Medicine and Philosophy* 5, no. 3 (1980): 215-24. See also N. King, G. Henderson, and J. Stein, ed., *Beyond Regulations: Ethics in Human Subjects Research* (Chapel Hill: University of North Carolina Press, 1999); and N. King and L. Churchill, "Clinical Research and the Physician-Patient Relationship: The Dual Roles of Physician and Researcher," in *The Cambridge Textbook of Bioethics* (Cambridge, U.K.: Cambridge University Press, 2007), 710-38. See also M. Easter et al., "The Many Meanings of 'Care' in Clinical Research," in *The View From Here: Social Science and Bioethics* (Oxford, U.K.: Blackwell, 2007), 30-47.

16. See R. Dresser, "The Ubiquity and Utility of the Therapeutic Misconception," *Social Philosophy and Policy* 19, no. 2 (July 2002), 271-94. See also M. Miller, "Phase 1 Cancer Trials: A Collusion of Misunderstanding," *Hastings Center Report* 30, no. 4 (July-August 2000): 34-43.

17. See A. Harmon, *http://topics.nytimes.com/top/news/health/series/target_cancer/index.html,* accessed 18 April 2013. See also the suggestions of therapeutic effects within the NIH website's information to patients: *http://www.nih.gov/health/whyparticipate/htm,* accessed 18 April 2013, which states that participants will "possibly receive the newest treatment."

18. S. Joffe and J. Weeks, "Views of American oncologists about the purposes of clinical trials," *Journal of the National Cancer Institute* 94, no. 24 (2002): 1847-53.

19. L. Churchill et al., "Assessing Benefits in Clinical Research: Why Diversity in Benefit Assessment Can Be Risky," *IRB: Ethics and Human Research* 25 (2003): 1-7.

20. R. Dresser, *When Science Offers Salvation: Patient Advocacy and Research Ethics* (New York: Oxford University Press, 2001). Also, Pamala Sankar notes that some principal investigators change their description of Phase I participation depending upon which cohort the patient-subject would enter, emphasizing safety in early dosing cohorts and potential benefit when enrollment would place a potential subject in a cohort receiving a higher dose. See P. Sankar, "Communication and Miscommunication in Informed Consent to Research," *Medical Anthropology Quarterly* 18 (2004): 429-44.

21. N. King et al., "Consent Forms and the Therapeutic Misconception: The Example of Gene Transfer Research," *IRB: Ethics and Human Research* 27, no. 1 (2005): 1-8; and N. King, "Describing and Defining Benefit Appropriately in Clinical trials," *Journal of Law, Medicine and Ethics* 28 (2000): 332-43.

22. G. Henderson et al., "Therapeutic Misconception in Early Phase Gene Transfer Trials," *Social Science and Medicine* 62 (2006) :239-53.

23. E. Emanuel, D. Wendler, and C. Grady, "What Makes Clinical Research Ethical?" *Journal of the American Medical Association* 283 (2000): 2701-11.

24. This valuable feature of informed consent is often overlooked. For a classic statement of its importance see A. Capron, "Informed Consent in Catastrophic Disease Research and Treatment," *University of Pennsylvania Law Review* 138 (1974): 341-429, see especially 669-72.

25. P. Appelbaum et al., "Therapeutic Misconception in Research Subjects: Development and Validation of a Measure," *Clinical Trials* 9 (December 2012): 748-61.

26. S. Joffe, "Quality of Informed Consent in Cancer Clinical trials: A Cross-sectional Survey," *Lancet* 358 (2001): 1772-7.

27. S. Horng and C. Grady, "Misunderstanding in Clinical Research: Distinguishing Therapeutic Misconception, Therapeutic Misestimation and Therapeutic Optimism," *IRB: Ethics and Human Research* 25 (2003): 11-16.

28. G. Henderson et al. "Clinical Trials and Medical Care: Defining the Therapeutic Misconception," *PLOS Medicine* 11, e324 (2007): 1735-8.

29. Ibid., 1737.

30. K. Weinfurt et al., "Research Participants High Expectations of Benefit in Early-Phase Oncology Trials: Are We Asking the Right Question?" *Journal of Clinical Oncology* 30 (2012): 4396-4400.

31. See note 1 above, p. 273.

32. See, for a good example, S. Koyfman, M. McCabe, E. Emanuel, and C. Grady, "A Consent Form Template for Phase I Oncology trials," *IRB: Ethics and Human Research* 31 (2009): 1-8.

33. R. Dresser, "Alive and Well: The Research Imperative," *Journal of Law, Medicine and Ethics* 40 (2012): 915-21.

34. See "Report, Ethical Oversight of Learning Health Care Systems," *Hastings Center Report* 43 (2013): S1-45.

Problems with the Consensus Definition of the Therapeutic Misconception

David S. Wendler

ABSTRACT

In a previous article,[1] I attempted to assess the likely impact of the most prominent versions of the therapeutic misconception (TM) on research subjects' informed consent. I concluded that the TM is not nearly as significant a concern as is commonly thought, and that focusing on it is more likely to undermine than promote research subjects' informed consent.

A recent commentary rejects these conclusions, as least as they pertain to the "consensus" definition of the TM.[2] The authors of the commentary argue that work on the TM remains central to ensuring the appropriateness of research subjects' consent and, by implication, the ethical acceptability of clinical research.

The present work evaluates the arguments offered in support of these claims. This analysis reveals that the authors offer few substantive responses to my arguments, and the responses they do offer fail to undermine my prior conclusions. Furthermore, consideration of an additional issue—the emergence of learning healthcare systems—suggests that the TM is likely to be even less significant in the future, hence, focusing on it may be even more problematic than I argued previously.

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INTRODUCTION

Many commentators have argued that, in order to ensure the ethical acceptability of clinical research, the therapeutic misconception (TM) must be reduced, and hopefully eliminated. Over the past 20 years, an enormous literature has attempted to explicate and defend this view. In contrast, there have been almost no analyses of all this work on the TM: What impact is this focus on the TM likely to have on the ethical acceptability of clinical research?

To address this gap in the literature, I attempted to evaluate the significance of the TM, and the likely impact of its most prominent versions on research subjects' informed consent.[3] I concluded that the TM is not nearly as significant a concern as is commonly thought, and that "emphasis on the TM is more likely to undermine than promote research subjects' informed consent." Unfortunately, Churchill, King, and Henderson (CKH) found my analysis fragmentary, often illogical, and ultimately reducing to the critique of a straw man.[4] The present work attempts to clarify my position and consider CKH's primary arguments against it. This analysis suggests that CKH do not offer any compelling reasons to question my prior conclusions regarding the significance of the TM. Moreover, consideration of an additional issue, the emergence of learning healthcare systems, suggests that focusing on the TM may be even more problematic than I argued previously.

BACKGROUND

Work on the TM is based on two central claims: (1) clinical research differs from clinical care in fundamental ways, and (2) it is vital for individuals involved in clinical research to understand these differences. To defend the two claims and establish the significance of the TM three questions need to be answered. Which fundamental differences between research and care need to be understood? Who needs to understand the differences? Why do the individuals in question need to understand the differences?

Those concerned with the TM answer these questions in different ways, leading to versions of the TM that differ in subtle and sometimes significant ways.[5] The existence of numerous versions brings us to the first puzzling aspect of work on the TM. There is widespread agreement that addressing the TM is vital to ensuring the ethical acceptability of clinical research, yet there is no agreement on what the TM amounts to in the first place. The present analysis attempts to avoid the confusion engendered by so many different versions of the TM by focusing on the version that is endorsed by CKH, what has been called the "consensus" definition of TM. The consensus definition holds that the TM occurs when "individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge."[6] The present analysis assesses the consensus definition of the TM as it pertains to research subjects. This focus will allow us to concentrate on the third, and most important question for establishing the significance of the TM: Why do research subjects need to understand the fundamental differences between research and care?[7]

A TASK-SPECIFIC APPROACH TO INFORMED CONSENT

It is widely agreed that research subjects' consent to participate in clinical research must be informed.[8] That is, to give informed consent, research subjects need to understand certain facts about the study in question, typically including its risks and potential benefits, the fact that participation is voluntary, and the alternatives. My previous article in *JCE* began with what seems the most straightforward way to ensure that research subjects understand these things. Specifically, I argued that investigators (and others) should identify which facts research subjects need to understand, disclose these facts, assess whether subjects understand them, and re-explain any facts that a particular individual did not understand the first time.

When determining what potential subjects need to understand, it is important to recognize that frequently they are choosing between participating in research and receiving clinical care. To make this choice, potential subjects often need to understand the relevant differences between the two options. This analysis suggests, consistent with work on the TM, that research subjects sometimes need to understand differences between research and standard clinical care. However, which facts potential subjects need to understand will vary from study to study. Consider a study that provides subjects with standard-of-care treatment for their condition, and takes two extra blood draws for research purposes. In this case, potential subjects should understand that, if they enroll, they will undergo two blood draws purely for research purposes that they would not undergo if they instead sought care in a clinical setting. In other instances, subjects might need to understand that enrollment in research involves receiving two doses of a drug rather than the standard one dose. And for some research studies, such as research with healthy volunteers, the differences between research and clinical care are irrelevant to informed consent.

An important virtue of such a "task-specific" approach to informed consent is that it recognizes that what subjects need to understand depends on the study in question. This contrasts with work on the TM, which tends to assume that most or all research subjects need to understand the same differences between research and clinical care. For example, according to the consensus definition, most or all research subjects need to understand the difference in purposes between research and clinical care.

A task-specific approach to informed consent also has the potential to address failures of understanding that arise from other sources. In the previous example, some subjects might not understand that research enrollment involves two "non-beneficial" blood draws because they are anxious; others might not understand this fact because they were not paying attention; still others because the investigator explained it using overly technical language. Given that there are many possible sources of misunderstanding, a task-specific approach first explains to subjects the facts they need to understand and then re-explains any facts that were not understood the first time. A task-specific approach attempts to identify and eliminate possible sources of misunderstanding only when a given subject does not understand one or more of the facts she or he needs to understand, following re-explanation. Many subjects who are anxious or who were not

paying attention will be able to understand the two non-beneficial blood draws following an explanation of this specific fact. The few who continue to misunderstand following re-explanation could be excluded, or the investigators could take steps to identify and address the source of the misunderstanding (for example, give the individuals some time to relax).

In effect, those concerned about the TM argue that investigators should reverse this order of explanation with respect to the TM. Investigators first should assess whether potential subjects have the TM. For potential subjects who do, investigators should explain the fundamental differences between research and care, and then make sure that the potential subjects understand these differences before explaining the study in question. For example, to implement this approach using the consensus definition, investigators would first explain that the defining purpose of clinical research is to collect generalizable knowledge, whereas the defining purpose of clinical care is to promote the health of the present patient. The investigators would evaluate whether the potential subjects understand these differences sufficiently and, once they do, then explain the facts about the study that the potential subjects need to understand to give informed consent. As far as I can tell, those concerned with the TM never explain why the TM should be treated differently than the many other possible sources of misunderstanding. The implicit assumption seems to be that the TM is more prevalent and that it is more likely to confuse research subjects than other potential source of misunderstanding.

The defining purpose of a joint activity is not a simple concept. The same is true for generalizable knowledge, and the possibility that one might obtain it by sticking a needle in the arm of research subjects. This complexity suggests that identifying and dispelling the TM in potential research subjects might consume a fair amount of time and resources.[9] CKH defend the use of these resources on the grounds that the fundamental differences between research and care are relevant to consent for most or all subjects. Thus, to evaluate their view, we need to consider whether most or all research subjects need to understand that the defining purpose of clinical research—but not of clinical care—is to produce generalizable knowledge.

WHAT IS THE PURPOSE OF RESEARCH?

Current U.S. regulations define research as a systematic investigation that is "designed to develop or contribute to generalizable knowledge."[10] On the assumption that the design of a given project is based on the purpose for which it is conducted, this definition suggests, consistent with the consensus definition of the TM, that the defining purpose of clinical research is to collect generalizable knowledge. At the same time, the collection of generalizable knowledge is not the only important purpose of many studies. To see this, imagine that the researcher in our previous example is the founder and owner of the biotech company that is sponsoring the study and his primary goal is to make a profit. When designing the study, he may prioritize earning a profit over collecting generalizable knowledge. For example, when deciding which individuals will be eligible for the study, he may choose inclusion criteria based on what will be most effective for marketing future products, not based on what will best yield generalizable knowledge. In this case, the primary goal of the investigator and the sponsor is to make a profit, suggesting that the primary purpose of the study is to make a profit, not to collect generalizable knowledge. And, given that the majority of clinical trials are sponsored by for-profit entities, this conclusion suggests that the consensus definition of the TM may not apply to many clinical trials.

CKH respond to this line of argument as follows: "What Wendler overlooks is that research has for a very long time been sanctioned and endorsed . . . as the pursuit of socially valuable . . . knowledge." As far as the history of clinical research goes, this seems right. However, it is not clear what this fact about the history of clinical research has to do with determining the purpose of clinical trials that are sponsored by for-profit entities. One possibility is that the authors are appealing to a distinction between the primary purpose of a study and the defining purpose. The primary purpose, meaning the purpose or goal that explains why the activity is being conducted, may be to earn a profit. However, the defining purpose, meaning the purpose or goal that defines the activity as research, is to collect generalizable knowledge.

While this response may seem appealing, it runs the risk of begging the question. The conclusion that the defining purpose of the blood draws is to collect generalizable knowledge traces to our having categorized the blood draws as part of a research study. For many purposes, this categorization makes sense. For example, it makes sense for U.S. research regulations to categorize the two blood draws as research, since their goal is to mandate guidelines for the conduct of research. However, there is nothing about the blood draws themselves that implies that they

must be categorized in this way. If we were instead interested in who owes taxes, we might categorize the blood draws as part of a for-profit venture. In this case, the defining purpose of the blood draws, categorized as part of a for-profit endeavor, would be to earn a profit for the sponsor.

This analysis reveals that the blood draws can be categorized in different ways, and these different categorizations are associated with different defining purposes. This conclusion becomes important once we realize that the investigator's and sponsor's goal of earning a profit may have as much, or even more of an impact on the design of the study than the goal of collecting generalizable knowledge. Moreover, the former goal may be more salient for potential participants who are less inclined to undergo extra blood draws to help others earn a profit, than to help others collect data that might benefit the health of future patients. These possibilities underscore the need for proponents of the consensus definition of the TM to explain why, for the purposes of respecting and protecting research subjects, it is more important to disclose that the blood draws involve research than it is to disclose that the blood draws involve a money-making venture. As far as I can tell, CKH do not offer such an explanation.

A further problem, that I did not consider in my previous work, concerns the recent development of learning healthcare systems. Specifically, there have been calls to redesign clinical care to systematically collect data on patients' outcomes.[11] In a learning healthcare system (LHC), encounters between clinician and patient are designed to both provide care to the patient and collect information that can be used to improve care for future patients. For present purposes, the important point is that learning healthcare systems are designed, in part, to collect generalizable knowledge.[12] This development seems to undermine the claim that research and care are fundamentally different because research, but not care, is designed to collect generalizable knowledge.

One way to defend the consensus definition of the TM in the face of this development would be to argue that collecting generalizable knowledge is a secondary goal of learning healthcare systems, whereas collecting generalizable knowledge is the primary goal of clinical research. Alternatively, proponents might argue that, in the context of LHC systems, some interventions will be designed primarily to benefit the present patient, while others will be designed primarily to collect data that might benefit future patients. The pill that patients take for hypertension will be designed primarily to improve their cardiovascular health, while the quality of life surveys they complete and the blood draws they undergo will be designed primarily to collect information to identify better ways to treat hypertension in the future. For present purposes, let us assume that proponents of the TM can effectively argue that, despite the blending of research and care that occurs in LHC systems, it will still be possible to categorize activities and interventions into those that are (primarily) clinical research and those that are (primarily) clinical care. At that point, the TM would be claiming that the ethical acceptability of clinical research depends on subjects understanding that the primary purpose of the procedures that fall into the category of research is to collect generalizable knowledge, whereas the collection of generalizable knowledge is only a secondary purpose of the procedures that are categorized as clinical care.

At first glance, it is not entirely clear why this distinction might be central to the ethical acceptability of clinical research. For example, imagine that the goal of earning a profit for the healthcare system has a significant impact on the design of an intervention. In that case, it seems important for individuals to be informed of this fact, whether or not the intervention ultimately falls on the research or care side of the divide. Similarly, the possibility that some individuals may be less willing to help others earn a profit, as opposed to helping investigators improve the health of future patients, would provide reason to regard the profit-earning motivation as something that individuals should understand, independent of whether the intervention is primarily research or care. The next section considers how proponents of the consensus definition of the TM might accept these conclusions, but nonetheless argue that most or all research subjects need to understand the (presumed) difference in defining purposes between research and care.

IS THE PURPOSE OF RESEARCH ITSELF AN ESSENTIAL ELEMENT OF CONSENT?

A plausible view holds that what individuals need to understand to give informed consent for a given study depends on how the decision whether to enroll in the study, rather than pursue one of the available alternatives, might affect the individuals' important rights and interests. For example, potential subjects should understand the risks of a study, because being harmed would set back their interests. In contrast, the purpose of research concerns the reasons why investigators and funders conduct it. They conduct it in order to collect generalizable knowledge. This raises the question of why, to the

extent that they are concerned with protecting research subjects' rights and interests, proponents of the TM are so interested in the goals or motivations or intentions of investigators and funders.

Perhaps the most obvious answer is that potential subjects need to understand that the study in question (or a given procedure within a learning healthcare system) involves research. And, to understand this, potential subjects need to understand that the goal of investigators is to collect generalizable knowledge. In an end note, CKH suggest this response when they claim that it is hard to imagine research subjects understanding that they are participating in research unless they understand that "research is, by definition, driven by the pursuit of generalizable knowledge."

In my original article I argued that, to understand that they are being invited to participate in research, potential subjects should "understand that they are being invited to participate in a project to help others, and that the investigators with whom they will interact are trying to benefit others." This analysis is supported by the fact that individuals have non-welfare interests in contributing to projects that are consistent with their moral beliefs. Knowing that they are being invited to contribute to helping others allows individuals to decide whether they want to make this contribution. Notice that this is important even in the context of activities whose defining purpose is something other than collecting generalizable knowledge. For example, even in the context of learning healthcare systems, there is a reason to inform patients that they will be contributing to a project to help others.

I suspect that this disagreement may be central to the debate over the significance of the TM. Yet, CKH do not mention, much less provide any reasons to question, my analysis regarding what research subjects need to understand in order to understand that they are participating in research.

IS UNDERSTANDING THE PURPOSE OF RESEARCH NECESSARY FOR OTHER REASONS?

The previous analysis undermines the claim that, in order to give informed consent, most or all research subjects need to understand the fundamental differences between research and care. A different defense of the consensus definition of the TM would be to argue that understanding the fundamental difference between research and care is not, itself, something that research subjects need to understand. Instead, understanding the fundamental differences between research and care is a necessary prelude to understanding the things that research subjects need to understand. For example, to understand the risks of research, subjects need to understand the fundamental differences between research and care. The possibility that this might be the basis for CKH's endorsement of the consensus definition of the TM is suggested by the following claim: "it is hard to see how understanding the other key elements would be intelligible unless subjects were clear on the central difference of purpose, which then provides context for all the particulars that need to be disclosed."

The most plausible version of this view holds that potential subjects need to understand the purpose of research in order to understand its risks and potential benefits. To evaluate this view, I considered the possibility of a subject being asked to undergo extra blood draws for research purposes. I speculated that many subjects will be able to understand the risks of the blood draws and the fact that the blood draws wouldn't help them, without necessarily understanding the defining purpose of research. CKH respond to this example by arguing, "Wendler's argument is difficult to follow, since an adequate explanation to subjects of the need for extra blood draws would entail an explanation that they are necessary to fulfill the larger aims of research and are not needed for this patient's care."

The claim here seems to be that subjects will not understand the risks of the blood draws and that the blood draws do not offer any potential benefit, unless the subjects understand their purpose. Yet, in many cases, it seems that individuals are able to understand a request to undergo two blood draws without understanding their purpose. Imagine that someone asks to obtain two vials of your blood through a needle for his or her own purposes. Presumably you could understand the risks and lack of personal benefits, even if you do not understand the individual's purpose for obtaining the blood. In particular, the risks of the blood draws are determined by the nature of the procedure, not its purpose. Likewise, many individuals likely will be able to understand the lack of benefit to them of a blood draw without understanding its purpose. They will be able to understand the negative—these blood draws will not benefit me—without understanding who or what might benefit from them. You might readily grasp that the blood draws offer you no potential benefit without knowing, and perhaps without caring, whether they are being done for research, to collect blood for an art project, or for a blood transfusion.

Proponents of the TM might respond that many or most potential subjects will inevitably assume that

the blood draws are being done for clinical care. Thus, without an explanation of the actual purpose, these individuals will assume that the blood draws offer them some potential for clinical benefit. Undoubtedly, there will be some individuals for whom this is the case. The research context includes aspects that tend to encourage this confusion. In particular, requests for research blood draws are often made by clinicians who wear white coats and work in hospitals. As a result, potential subjects may assume that the blood draws are being done for their clinical care.

One way to try to address this concern would be to explain to potential subjects the defining purpose of research and how the blood draws help to promote that purpose. A more straightforward approach that I endorsed in my previous article would be simply to ask potential subjects, after the disclosure process, whether the blood draws offer them any chance for medical benefit. For those who think they do, the investigators could emphasize that they are not being done for clinical care and they do not offer any chance of benefit to subjects. I speculated that many subjects will understand this the first time it is explained to them, and many of those who do not understand it the first time will understand it following a targeted explanation. CHK disagree. They believe that many potential subjects will suffer from the TM and many, perhaps most, of these individuals will fail to understand the risks and potential benefits of research participation.

At this point, debate over the significance of the TM becomes an empirical one. To defend the significance of the TM, its proponents need to show that many, perhaps most, potential research subjects have the TM, and that the presence of the TM makes it very difficult or impossible for many individuals to understand the things they need to understand to give consent. Imagine that there are 100 potential subjects for a study that involves two extra research blood draws. Proponents of the TM assume that many individuals, perhaps 60, will have the TM and that, as a result, many of them, say 40, will continue to believe the blood draw is for their benefit, even after an investigator explains to them, and then re-explains, that this is not the case. My suspicion is this will be true for, at most, a handful of the 100 potential subjects. As far as I am aware, no one has collected the data needed to resolve this disagreement. Hence, in my previous article, I described a study that could be used to collect the relevant data.

Briefly, the study would randomize potential subjects to either a task-specific or TM-endorsed consent process. The task-specific approach would explain the facts that subjects need to understand, and then re-explain any facts that were not understood the first time. The TM-endorsed approach would first identify which subjects have the TM and then try to eliminate it. This approach would then explain the facts that subjects need to understand. The study would evaluate how long the two processes take and what percentage of individuals in the two arms understand the facts that they need to understand to give consent. Surprisingly, CKH do not mention this proposal in their commentary on my article, nor do they provide any reason to think that the results will support their view. Hence, to determine whether it is time to stop worrying about the TM, an important step will be to start collecting the relevant data.

THE RESEARCH RELATIONSHIP

Work on the TM is rightly concerned with protecting the rights and interests of research subjects. To promote this goal, proponents of the consensus definition of the TM argue that it is important for research subjects to understand the differences in defining purposes between research and clinical care. Bracketing for the moment the specific problems we have been considering with the consensus definition of the TM, this focus may seem puzzling. What do the goals or motivations of investigators and funders have to do with protecting subjects? The answer is suggested by a passage in which CKH argue that my analysis regarding the relative unimportance of the TM fails because I neglected a critical feature that distinguishes clinical care from clinical research. I quote them at length because their claim may point to the fundamental concern that underlies work on the TM:

> The idea that the people I am relating to in a clinic or hospital setting are all here to help me, that they have my welfare primarily in mind, is the default assumption of our relationships with doctors and nurses. In research this assumption is false; this is the central phenomenon of the TM. . . . As patients we are often comfortable with much that is left unsaid about procedures and interventions, precisely because we are secure in an understanding that our benefit is the primary professional motivation. Research interactions require a great deal more in terms of negotiation and consent precisely because this core fiduciary value cannot be taken for granted. That our trust in physicians may at times be misplaced—perhaps because of the parallel influences on the treatment relationship that arise

from the larger context of healthcare delivery, that Wendler discusses only in reference to research—does not alter the need to attend most carefully to the research relationship.

The basic idea here seems to be that confusing research with clinical care is troubling because clinicians are motivated primarily to help their patients, whereas researchers are motivated primarily to collect data. As a result, participation in research is much more risky overall than receiving clinical care. Clinicians are focused on protecting us; the concerns of researchers lie elsewhere. On this view, identifying and eliminating the TM is important as a way to put overly trusting subjects on their guard. This suggests a possible reason that proponents of the TM focus so much on the goals or motivations of investigators and funders. Even if, as I have argued, many subjects will be able to understand the risks of research procedures, it is nonetheless important for subjects to understand the fundamental differences between the purposes of research and care; this understanding alerts subjects that they largely have to protect themselves.

While the claim that clinical research is much riskier than clinical care makes sense, there are good reasons to think it is mistaken. First, as I argued previously, many investigators are motivated to help their subjects. I have personally interacted with hundreds of researchers who are very concerned for the welfare of their subjects. This concern likely provides important protection for research subjects. And, although I am not aware of any data to this effect, I suspect that some clinicians are not primarily motivated to benefit the patient in front of them. Instead, they are motivated to have a career or make a living, and the treatment of patients is a means to achieve their goals.

Of course, many clinicians are concerned with the welfare of their patients. However, the goals of having a career and making money can put patients at risk to a greater extent than the goal of collecting data places research subjects at risk. For example, the motivation to have a career can lead surgeons to accept cases for which they are less prepared or equipped to perform than a colleague may be, thus posing increased risk to patients that may be greater than the levels of net risk that are permitted in clinical research.

Second, as mentioned previously, the development of learning healthcare systems that are designed to provide clinical care and simultaneously collect data has the potential to undermine the presumed difference between research and care. Physicians who are trained within a learning healthcare system will be motivated both to help the present patient and to collect data to help future patients. Third, even if we grant that there is a difference in the primary motivations between physicians and researchers, it does not necessarily follow that research participation is always riskier. There are many other differences between research and care that can affect their respective risks. Investigators are subject to significantly more oversight than personal physicians, including oversight by institutional review boards (IRBs) that must review their studies every year. And oversight may be more important in terms of protection than the motivations of clinicians and investigators. In addition, investigators tend to be relatively expert with respect to the condition under study. This level of expertise almost certainly protects and benefits subjects compared to patients, many of whom are seen by clinicians whose knowledge and skills are below average.

Finally, significant harms to research subjects typically have greater negative consequences for researchers than harms to patients have for clinicians. For example, the development of a new treatment can cost hundreds of millions of dollars and take a decade. Significant harm to even a few subjects can undermine and even derail an entire research program. In this case, because researchers are motivated to develop new treatments, and because many of them are motivated to make money, they may be very protective of research subjects.

CONCLUSIONS

To give informed consent, research subjects typically should understand the central features of the study in question as they relate to their rights and interests (for example, that enrollment involves research, the risks, the potential benefits). CKH's defense of the TM, and their rejection of my prior arguments, seems to be based on the claim that it is difficult or impossible for many individuals to understand these things unless they understand that the purpose of research, but not the purpose of clinical care, is to collect generalizable knowledge. I have argued that CKH do not provide a compelling defense for this view. In particular, the emergence of learning healthcare systems undermines the claim that clinical care is not designed to collect generalizable knowledge. In addition, even when this difference exists, it is irrelevant to informed consent in some cases (for example, research with healthy volunteers) and may be less relevant than other con-

siderations (whether a study is for-profit or not). Finally, I have argued that the TM is only one source of possible misunderstanding, that it may not be the most important source, and that most potential subjects will be able to understand what they need to understand to give informed consent without understanding that research and care have different defining purposes. This analysis suggests that identifying and eliminating the TM will be important for, at most, a small subset of research subjects. To support the consensus definition of the TM at this point, its proponents need to provide reasons to think that it accurately characterizes the fundamental difference between research and care, including learning healthcare systems, and reason to think that a significant percentage of potential subjects will not be able to understand what they need to understand unless they understand this difference.

NOTES

1. D.S. Wendler, "Time to Stop Worrying about the Therapeutic Misconception," *The Journal of Clinical Ethics* 23, no. 3 (Fall 2012): 272-87.

2. L.R. Churchill, N.M.P. King, and G.E. Henderson, "Why We Should Continue to Worry about the Therapeutic Misconception," in this issue of *JCE.*

3. Wendler, see note 1 above.

4. Churchill, King, and Henderson, see note 2 above.

5. As a result, grappling with the TM can feel like grappling with Proteus, who, in his attempts to escape Menelaus, changes into a "lion with a great mane; then all of a sudden he became a dragon, a leopard, a wild boar; the next moment he was running water, and then again directly he was a tree." Homer, *The Odyssey,* 800 B.C.E, translated by Samuel Butler, *http://classics.mit.edu/Homer/odyssey.4.iv.html,* accessed 10 May 2013.

6. G. Henderson et al., "Clinical Trials and Medical Care: Defining the Therapeutic Misconception," *PLOS Medicine* 11, e324 (2007): 1735-8. Although not stated explicitly, the consensus definition of the TM includes a suppressed clause that the defining purpose of research, but not of clinical care, is to collect generalizable knowledge.

7. This limitation, which is consistent with my previous article, allows us to evaluate the original, as well as the most prominent versions of the TM. However, in response to my arguments, CKH suggest that the TM may be more important to the extent that it affects "investigators, the media, the general public, and the institutions and organizations that oversee and sponsor research." To support this claim, CKH point out that IRBs around the world approve trials in order to have something to offer patients for whom all else has failed. As stated, this practice does not strike me as necessarily problematic, much less a claim on which to base one's defense of the TM. Depending on the circumstances, this might be just the right thing for IRBs to do. With respect to investigators, the authors' concern seems to be that investigators do not always act in ways that are consistent with the goal of developing generalizable knowledge. For example, they point out that investigators sometimes deviate from the goal of collecting data in order to help subjects, and, there is "considerable evidence that physicians not infrequently refer patients to trials with the intent and expectation that a trial is the best treatment." This version of the TM seems to be more about the behavior of investigators and funders than the understanding of research subjects. If that is right, this version will require a new consensus definition of the TM. In addition, this version has the potential to lead proponents into ironic waters. As I argue below, the primary motivator of work on the TM seems to be protection of subjects from the risks associated with collecting data. In the present case, the concern seems to involve actions that deviate from the collection of data in order to benefit subjects. See the authors' statement: "Yet because benefiting patients who are subjects seems virtuous, the risks of harm arising from investigator TM may be far less visible and thus potentially more damaging." The risks they have in mind here seem to concern the validity of the scientific results of research studies, rather than the well-being of its subjects.

8. This agreement is widespread, but not unanimous. For example, some commentators argue that subjects need not understand the study in question; all that is required is adequate disclosure on the part of investigators.

9. In a recent work, Appelbaum and colleagues propose an instrument that might be used to identify the TM among research subjects: P. Appelbaum et al., "Therapeutic misconception in research subjects: development and validation of a measure," *Clinical Trials* 9 (December 2012): 748-61. In an accompanying commentary, I attempted to estimate the practical impact of their approach, including the time that would be required to implement it: D. Wendler, "Taking the measure of the therapeutic misconception," *Clinical Trials* 9 (December 2012): 762-4. In their response to my comments, Appelbaum and Lidz claim that their endorsed approach may not be as time-intensive as I suggest. P.S. Appelbaum and C.W. Lidz, "The mismeasure of therapeutic misconception," *Clinical Trials* 9 (December 2012): 765.

10. "Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects," 45 *CFR* 46, 2009, *http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html,* accessed 5 November 2013.

11. L.A. Olsen, D.R. Aisner, and J.M. McGinnis, *The Learning Healthcare System: Workshop Summary,* Institute of Medicine of the National Academies Roundtable on Evidence-Based Medicine (Washington, D.C.: National Academies Press, 2007), *http://books.nap.edu/openbook.php?record_id=11903,* accessed 5 November 2013.

12. R.R. Faden et al., "An ethics framework for a learning health care system: a departure from traditional research ethics and clinical ethics," *Hastings Center Report* 43 (2013): S16-27.

Personal Perspective

Modern Clinical Research: Guidelines for the Practicing Clinician or Source of Confusion?

Ilia Volkov

ABSTRACT

There is a dilemma in modern medicine, and, as a general family practitioner, this dilemma has great impact on me as a professional with a responsibility to my patients, and on the treatments I prescribe. Every day we receive a lot of updated information about relevant issues in treatment of various conditions we encounter in our daily practice. There is a great deal of interesting, serious research; however, frequently results and conclusions are very different and at times, contradictory. It is extremely difficult to evaluate updated research information, and to understand trends in current medicine. Our responsibility to our patients is to find a solution for this problem.

There comes a time in our lives that we feel the need to take account. There is a dilemma in modern medicine, and, as a general family practitioner, this dilemma has great impact on me as a professional with responsibility to my patients, and on the treatments I prescribe. I wish to share this dilemma with you.

Leonardo da Vinci is reported to have said, "Simplicity is the ultimate sophistication." In this article I will not propose multifaceted sophisticated thoughts, but rather I would like to initiate a simple discussion of some problems we encounter in our daily activities as physicians, for which the solutions may need to be sophisticated and complex. Some of my thoughts will be of interest and useful for those of my colleagues who, after accumulating extensive experience can identify with my dilemma, as well as for doctors who are just beginning their professional careers.

I have been a physician for 25 years, a family physician, and, as we all do, I update my formal education with the current status of and advancements made in research, and I have become aware of a problem concerning basic treatment for my patients.

Modern medicine is very dynamic. Every day we receive updated information about relevant issues in treatment of various conditions that we encounter in our daily practice. There is a great deal of interesting, serious research; however, frequently results and conclusions are very different and, at times, contradictory. It may seem peculiar, but sometimes I feel a sense of nostalgia for the good old days, when we practiced medicine based on research that might have been inconclusive, and/or at best speculative. As a rule only a few of the results were significant, even though the design and logic were impressive: a random sample, researched and reported by a serious team of scientists and physicians, from reputable clinics. The conclusion of the research

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included determined guidelines for a long-term treatment strategy, and the principles were clear to clinicians.

What about today? In the morning I read the results of a new, highly reputable study, with recommendations to change a treatment strategy for a particular ailment, and in the evening or the next day I read a different conclusion of other experimentation regarding the same ailment. How does this affect me and my patients? Both studies are written by reputable research teams. Usually they are double-blinded, placebo-controlled studies that are conducted in large clinical centers, and their results published in good professional journals. The problem is to choose the right treatment for the patient and avoid complications and contradictions.

Here is an example of an analysis of recommendations/guidelines for using aspirin as a preventative measure in cardiovascular events. This is a chronological account of research conclusions and recommendations from respected medical journals.

2004: "Despite daily aspirin treatment, many patients break through aspirin treatment and experience cardiovascular events."[1]

2005: "In this large, primary-prevention trial among women, aspirin lowered the risk of stroke without affecting the risk of myocardial infarction or death from cardiovascular causes."[2]

2006: "For women and men, aspirin therapy reduced the risk of a composite of cardiovascular events due to its effect on reducing the risk of ischemic stroke in women and MI [myocardial infarction] in men."[3]

2007: "Aspirin resistance, defined by an aggregation-based rapid platelet function assay, is associated with an increased risk of adverse clinical outcomes in stable patients with CAD [coronary artery disease]."[4]

2008: "In this study of patients with type 2 diabetes, low-dose aspirin as primary prevention did not reduce the risk of cardiovascular events."[5]

2009: "Aspirin reduces the risk for myocardial infarction in men and strokes in women."[6]

2010: "The administration of aspirin compared with placebo did not result in a significant reduction in vascular events."[7]

2011: "Aspirin was ineffective or even harmful in the majority of patients."[8]

2012: "Our study shows that among diabetic patients without previous vascular events, statins but not aspirin reduce thrombotic risk."[9]

What can we conclude? Aspirin—yes or no? Other examples could be found concerning control of diabetes mellitus, the use of B-blockers, psychiatric medications, different vitamins, et cetera.

No doubt the achievements in modern medicine depend on medical research, and clinical guidelines base their recommendations from evidence based upon this research, but today, for practitioners, it is extremely difficult to evaluate updated research information, and to understand trends in current medicine. Our responsibility to our patients is to find a solution for this problem.

NOTES

1. H. Arjomand, M. Cohen, and M.D. Ezekowitz, "Combination antithrombotic therapy with antiplatelet agents and anticoagulants for patients with atherosclerotic heart disease," *Journal of Invasive Cardiology* 16, no. 6 (May 2004): 271-8.

2. P.M. Ridker et al., "A randomized trial of low-dose aspirin in the primary prevention of cardiovascular disease in women," *New England Journal of Medicine* 352 , no. 13 (31 March 2005): 1293-304, epub 7 March 2005.

3. J.S. Berger et al., "Aspirin for the primary prevention of cardiovascular events in women and men: a sex-specific meta-analysis of randomized controlled trials," *Journal of the American Medical Association* 295, no. 3 (18 January 2006): 306-13.

4. W.H. Chen et al., "Aspirin resistance and adverse clinical events in patients with coronary artery disease," *American Journal of Medicine* 120, no. 7 (July 2007): 631-5.

5. H. Ogawa et al., "Japanese Primary Prevention of Atherosclerosis With Aspirin for Diabetes (JPAD) Trial Investigators. Low-dose aspirin for primary prevention of atherosclerotic events in patients with type 2 diabetes: a randomized controlled trial," *Journal of the American Medical Association* 300, no. 18 (12 November 2008): 2134-41, epub 9 November 2008.

6. T. Wolff, T. Miller, and S. Ko, "Aspirin for the primary prevention of cardiovascular events: an update of the evidence for the U.S. Preventive Services Task Force," *Annals of Internal Medicine* 150, no. 6 (17 March 2009): 405-10.

7. F.G. Fowkes et al., "Aspirin for Asymptomatic Atherosclerosis Trialists. Aspirin for prevention of cardiovascular events in a general population screened for a low ankle brachial index: a randomized controlled trial," *Journal of the American Medical Association* 303, no. 9 (3 March 2010): 841-8.

8. J.A. Dorresteijn et al., "Aspirin for primary prevention of vascular events in women: individualized prediction of treatment effects," *European Heart Journal* 32, no. 23 (December 2011): 2962-9

9. A. Macchia et al., "Statins but Not Aspirin Reduce Thrombotic Risk Assessed by Thrombin Generation in Diabetic Patients without Cardiovascular Events: The RATIONAL Trial," *PLoS ONE* 7, no. 3 (March 2012).