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At the Bedside

Slowing Down Fast Thinking to Enhance Understanding

Edmund G. Howe

ABSTRACT

Stress can make the comprehension of complex information more difficult, yet patients and their family members often must receive, process, and make decisions based on new, complex information presented in unfamiliar and stressful clinical environments such as the intensive care unit. Families may be asked to make decisions regarding the donation of organs and genetic tissue soon after the death of a loved one, based on new, complex information, under tight time limits. How can we assist patients and families to better process complex information while under stress, and make better decisions for themselves or a loved one?

In this issue of *The Journal of Clinical Ethics*, in "Impact of Cognitive Load on Family Decision Makers' Recall and Understanding of Genotype-Tissue Expression (GTEx) Project Donation Requests," Laura A. Siminoff, Heather M. Traino, Maghboeba Mosavel, Howard M. Nathan, Richard D. Hasz, Jennifer Trgina, K. Laura Barker, Maureen Wilson Genderson, and Gary Walters discuss how clinicians can help patients and families better understand requests for donations of genetic tissue. The authors recommend strategies to help clinicians and researchers provide complex information to any person who is under stress, as, for example, patients and family members who struggle to make decisions in an intensive care unit (ICU).[1]

But even when information is shared in the best possible way, patients, families, and most anyone who is in a stressful situation may not understand as well as they might when they are calmer. Emotions such as fear can decrease our capacity to think carefully. Due to fear or another strong emotion, we may have a fight-or-flight-like response or feel emotionally paralyzed on receiving new information. Other emotions such as hate and even love may also cloud our capacity to accurately understand. When we hate, we may automatically and immediately dismiss what another says, and, when we love, see all that our loved one says as rose-colored. Our emotional responses may be all-important and adaptive. But when we must think more carefully, the intuitive, automatic, and unreasoned responses that feelings can engender may "hijack" our capacity to reflect more deeply. Thus, when this occurs, it may leave us wholly dependent on what our feelings "tell us." Daniel Kahneman describes this hijacking in detail in his recent book on what he calls "fast and slow thinking." Our faster, intuitive thinking system is, he says, more influential than our slower reasoning. This faster system he says, is not readily educable."[2] Thus, this may be a *second* obstacle to patients' and family members' understanding.

Therefore, in this article, I will discuss several ways that we can help to reduce patients' and fam-

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ily members' fast thinking, so that they can make decisions that better reflect their genuine needs, over the long run.[3] I will do this in three sections. In the first, I discuss fast and slow thinking more generally. A critically important aspect of the concept is that when we engage in fast thinking, we may not know that we seem to be locked into that state. As Kahneman says, we may search for plausible reasons for what we feel, and then believe the stories we may "make up" as a result.[4] But immediate intuitions may seem miraculous and even lifesaving, for example, a fireman who senses hidden, imminent danger and saves himself and his crew, or a physician who makes a complex diagnosis after a glance at a patient. Kahneman points out that these seemingly magical insights may be nothing more than subtle cues that trigger associated memories.

When intuition or fast thinking determines our response without our knowing it, it can leave us exceptionally vulnerable to making suboptimal decisions without realizing it. We may later deeply regret what we decided. In this first section I will give three case examples in which patients who knew about fast thinking became less vulnerable to such hijacking. The cases illustrate the risks of fast thinking and the possible gains of alerting patients and family members to this concept before we discuss with them the treatment choices they have to make.

In the second section, I will discuss how we may be able to assist patients and families when they confront ethical decisions involving genetics. Our capacity to see patients' fast thinking may itself be impaired by our own fast thinking. The two issues I will principally address are how we might help patients decide whether they want to be screened for genetic disease, and whether they want to give information about their genes to biologically related relatives who could benefit from it. I will address some policy questions that involve genetics, parents, and children to illustrate how fast thinking may influence determinations of policy.

In the third section I will consider several ways that we can help reduce families' fast thinking in the ICU, so they can better understand new information when we use the approaches Siminoff and colleagues recommend. The ICU is one of the more stressful settings these authors mention. If we can help to reduce family members' fast thinking in this setting, they should do better and may make better ethical decisions regarding their loved one.

It may seem, from this description of what I will address, that I am downplaying the importance of what patients *feel* and the importance of the fast thinking that their emotions may evoke. Emotions may be critically important in helping patients to discern what they need and want, and their emotions may do this by helping them narrow and frame their options. Then, using slow thinking—our reasoning—we may attend to what our patients have discerned. Fast thinking may be markedly adaptive and further better solutions in countless situations.

FAST AND SLOW THINKING

Fast thinking is likely to occur immediately in response to a stressful event, although it may provide immediate insights, as exemplified by the example of the physician who saw at once a patient's complex diagnosis. But when fast thinking is emotionally driven, fast thoughts may replace logic. Fast thinking and logic may become mutually exclusive thought processes, and may function as parallel lines or brain circuits that never meet. Decisions we make when we are affected by fast thinking, in response to a stressful situation, may, though, *feel* right. As Kahneman writes (citing the psychologist Jonathan Haidt): "The emotional tail wags the rational dog."[5] This suggests that what patients and family members *do* may not be at all what they really most *want.* What they want may lie outside their awareness and not be able to be known to them. What their feelings suggest may be tragically misleading, and they may come to bitterly regret their choice. As Quist wrote, "individual defense mechanisms and habits of thought" may be ". . . least accessible to introspection or self-reflection as participants struggle to keep the external world consistent with their internal world. . . ." People "get themselves wrong, what they want and lack . . . we *all* get it wrong."[6]

Triggers of Fast Thinking: Cues and Risks

An important aspect of fast thinking is how it may occur in response to a visual cue. For example, if we see something we find shocking, that strong emotion may create a memory that *stays with us*. That it may stay with us has enormous implications, because a visual event may greatly skew what we decide in the moment, and it may continue to determine what we decide over time—and perhaps for the rest of our life. An example of such a visual cue is when a surgeon deliberately set out to shock a parent to save a child's life. The boy's leg had become terribly infected, and he would die unless it was amputated. The boy's mother, however, refused to consent. The surgeon took her to the boy's bedside, removed his bandages, and showed her the open wound. After he did this, the mother consented, and her son survived. This is not to recommend that clinicians do this routinely; instead I mean it to show how visual cues may trigger fast

thinking and how powerful that can be, even overthrowing strongly held prior concerns, as in this case. There are many cues that can trigger fast thinking; visual cues are only one.[7]

Our visual system may, however, "trick us," as when we are duped by a visual illusion. Kahneman refers to this phenomenon metaphorically when he posits how we might best respond to such treachery, using a well-known Müller-Lyer visual illusion as an example. Viewers of the illusion are asked to mark the middle of a horizontal arrow on a page, but invariably draw a mark toward closer to the arrow's tail. Kahneman suggests that we should not trust our impression of the arrow's length in this exercise, and we should do likewise when we encounter possible products of our own fast thinking.

A cue that triggers fast thinking may be, for example, no more than the memory of what a loved one said about an illness and treatment she or he had. Or it may be no more than a report by a stranger on the internet. As Kahneman notes, we may feel optimistic, but not know why, because something reminds us of a beloved sister, or we may dislike a person because he or she looks vaguely like our dentist.[8] We may have no idea why we want what we want. Visual cues trigger fast thinking, but the cue that is most likely to negatively affect us is an exaggerated fear of, and thus reluctance to take, actions with possibly adverse results. This fear is common. As Kahneman puts it, "if a potential outcome is framed as a *loss*, it may have more impact than if it is presented as a gain."[9]

How an exaggerated aversion to risk may begin is illustrated by an example using percentages of gain and loss. For instance, if a procedure to treat back pain is presented as having a 50 percent chance of success, we are more likely to agree to it than if it is presented as having a 50 percent chance of failure. An orthopedic surgeon recently suggested that all clinicians who perform the same procedure should use the same words when they inform patients about it, and convey potential gains and losses as percentages. This would reduce, he proposes, the risk of triggering the above, irrational result.[10] Doing this may well help reduce patients' confusion regarding relative and absolute risks. In the next section I will present three clinical examples that illustrate another way we may be able to help reduce this possible source of irrational thinking for patients. The approach can have surprisingly rapid results.

Clinical Examples

We can inform patients about fast and slow thinking and that fast thinking may adversely affect them, as it does to everyone. With this knowledge, they may be better able to decide what they want for themselves. The following two examples involve patients I have seen. I will refer to them by well-known characters in our Western culture. This may help readers capture and remember them.

King Lear. The first patient I will refer to as King Lear. Lear is the main character in the Shakespearean play of the same name. He had two daughters whom he believed had greatly wronged him. The patient I saw felt greatly wronged by his daughter. For this reason, he thought that he possibly or probably wanted to disinherit her. Yet he also felt ambivalence. "After all," he said, "she *is* my daughter." He felt miserable and, in his own words, "*stuck*." I explained to him about fast and slow thinking, and I suggested that, based on what he'd said, it might be that he was stuck between fast and slow thinking. His daughter's wrongdoing may have triggered his anger, and the resulting fast thinking—although it was triggered decades earlier—may have remained; whereas his *not* wanting to disinherit his daughter might represent his present slow thinking.

My interest, I said, was not to influence him to decide one way or the other, but solely to try to help him free himself from the painful ambivalence in which he reported himself stuck. I hoped, I said, that this new knowledge of fast and slow thinking might help him better decide what he now really most wanted. It seems this is what then occurred: he suddenly, he said, *knew* what he wanted. He wanted to include his daughter in his will, although she had wronged him decades before. She was, he said, after all, his only child, his only daughter.

The Prodigal Son. A second example also involves a father. He had given his son an inheritance early. I will refer to the son as the Prodigal Son, since, like the character in the Bible, he had squandered the wealth that his father gave him, and then returned feeling great remorse.[11] Like the patient I called King Lear, this father was wracked with ambivalence. He was furious at his son for having squandered his early inheritance, but, at the same time, had positive feelings for him. He felt that morally, though, he had no choice but to "disown" him.

I explained to the man how fast and slow thinking work. When saying this, I acknowledged that these two types of thinking take place in all of us. I said this to try to be surer that he knew I was speaking about people in general, and not only about him. This additional statement is an approach I use often and believe that clinicians and ethics consultants should apply more widely. I anticipate the possible ways that what I say may be ambiguous and may be misinterpreted by patients and families. Anticipating this, I can say what I *won't* mean first.

In the above case, I clarified that my explanation was not a comment about this patient, more than any other person, but rather, that fast thinking is a tendency that is universal, and information about fast thinking was something that he, at that time, might find particularly helpful. The patient reported that after I had described fast and slow thinking, his anger at his son abruptly vanished. In its place he had, he said, a "sudden flash of insight." He realized at that moment, he said, that his son's remorse was an expression of the *person* his son was, and that squandering his inheritance was a "human" mistake. This father said that, "deeper down," he most loved his son for his remorse: "People make big mistakes," he said. "*I* have."

One might wonder how it could be that these two patients, just learning about fast and slow thinking, could change their views and emotions so fast. The answer is that just as emotions can hijack slow thinking, a capacity for one part of the brain to influence another goes both ways. A new awareness can change what we feel, and quickly.

To illustrate to patients that this is possible, I may share with them, prior to doing therapy that may alter their thinking, the following exercise. I ask them to imagine that they are the last person to enter an elevator and they enter backwards, and the elevator door closes close to the tip of their nose. I ask them to imagine next that they feel a hard, round object pressing against them, into their lower back. I suggest that they feel irritated that the person behind them doesn't notice this, and doesn't stop it. I suggest that as the elevator opens at the next floor, they turn and see the person behind them. They see that the person behind them is blind, and the hard, round object pressed against them is the halter of a seeing-eye dog. Patients say they immediately lose the feeling of being annoyed, and may even feel a tad ashamed. I share with patients how, likewise, having a new thought may change their emotions, and how this, in turn, may help them feel better.

These examples may be misleading; I have "cherry-picked" successes. It may be that with the two above patients, explaining fast and slow thinking had little or no effect, but may have occurred due to other factors. In other parts of their brain, functions bent on the underlying agenda of finding some way to reconcile the past wrongs of their child may have played a primary role.

In any case, this approach can be included in ethics consultation. That is, we can say *why* we will do something before we do it. In the last section of this article, I suggest that, in the ICU. we can tell patients' family members why they are being asked to gather for a special meeting, before we ask to have a meeting. As I will relate, doing this may do much to relieve a family's possible stress. Telling patients and families beforehand why we do what we will do may not only help them to see the underlying rationale, it may help them to understand more clearly what is going on. Then they may be more likely to respond in a way that helps the medical team and themselves. Sharing our rationale with patients and families helps us to work more as co-equal partners, which may reduce their possible perception that they are at the lower end of a top-down relationship, which may add to their fear. For example, I shared with King Lear and the father of the Prodigal Son why I told them about fast and slow thinking—it might help them slow down their thinking—and that explanation may have allowed them to use this new awareness more effectively.

A Colleague Who Had this Awareness Already. A colleague shared with me what she had done on her own. She knew about fast and slow thinking and used this awareness to change what her fast thinking initially had "decided." She told me not only that I could share her story with others, but urged me to do so, because she believed that what she did for herself might be helpful to others. She had breast cancer. Upon learning this, she knew exactly what she would do. She would do just what her mother had done. Her mother too had breast cancer, and she survived it. She had both breasts removed and later had no breast reconstruction. Then my colleague tried to make herself "slow think." "What do I want for *myself*?" she asked. She decided to have only one breast removed. She decided she wanted to retain her other breast so she would be able to sexually respond in this area. She also chose to have the breast that was removed reconstructed. An additional aspect of her experience warrants mention: throughout this experience she visited many different doctors. None raised the question of whether she would value retaining her sexual responsivity. This clearly is a need or want that clinicians might mention.[12] She now lives—and lives well—although she knows that her cancer could recur at any time.

She told me about an approach she uses that helps to reduce her fear that the cancer will return that is worth reporting. She draws a horizontal line across a piece of paper, and then writes above the line the factors in her life that she can't control. Below the line, she writes out the factors that she can control. Seeing in print what she can't control—for example, whether her cancer will recur—helps her, she says, accept that this risk is beyond her control. It helps her to reduce her fear and even, one might say, to deny it. The positive effect of being able to deny such a risk I will discuss shortly in consider-

ing how to explore with patients whether they think they can deny a risk of having dementia.

My colleague's use of drawing a horizontal line illustrates again how a visual cue can trigger fast thinking. In this instance, a visual cue is put to positive use, rather than spurring biased thinking. Another positive use of a visual cue, as mentioned above, is the surgeon who intentionally showed a woman her son's wound, to try to save the boy's life. Kahneman notes that it is easier to see the problems that fast thinking can bring about than to solve the problems. He asks, "What can be done about these biases?" and answers, "The short answer is . . . little . . . without a considerable investment of effort."[13] Kahneman says, more generally, that "The way to block errors . . . is simple in principle: recognize the signs that you are in a cognitive minefield, slow down, and ask for reinforcement from your [slow thinking]." As my colleague's personal experience suggests, the task of not just seeing, but resolving, these problems with the use of a visual cue may trigger positive gains from fast thinking. Clinicians are now encouraged to write down recommendations that are not ones we would normally write out, as a prescription. For example, recommending that our patients exercise several times a week, or write down each morning three things they are grateful for, may be more effective in moving patients to do these beneficial acts than just saying to do them. The visual effect of writing, it is believed, may have more therapeutic clout than just saying something.

It may be that urging such a self-practice would not affect patients significantly, and telling our patients about fast thinking wouldn't affect them significantly either. But input from just one other person may pierce others' defenses and move them to change. We may bolster patients and family members as they resolve their problems, such as reducing their fear, by offering our strong, felt support. With the support of just one other person, they may be able to resist making a decision that is driven by fast thinking, and can choose instead what, over the longer run, they want more. This may be what occurred with King Lear and the father of the Prodigal Son.

When patients and family members say they feel compelled to make a fast decision, we may alert them to other approaches that may help. Should they have a recurrent worry created by a visual cue, we can suggest they distance themselves from it by quantifying an aspect of it, for example by grading the intensity of the recurrent worry on a scale of one to 10. Patients and family members who continue to experience painful intrusive thoughts created by fast thinking may gain some relief by writing about their deepest feelings.[14] Trying to directly suppress unwanted thoughts is unlikely to provide relief.[15]

My colleague who draws a line on a piece of paper in response to her fear that her breast cancer will return has an excellent capacity to use the psychological defense of denial. In the next section I will consider how helpful denial may be to patients deciding whether to undergo genetic screening. If they have a strong capacity for denial, they may fare better without genetic knowledge that may be troubling, such as whether or not they have early signs of a disorder such as dementia. Using denial, they may be more able to continue to enjoy their life.

Whether or not patients have a capacity to use denial in this way may be the most critical question we can explore with them, to decide *together* whether they should undergo genetic screening or preliminary memory testing. While this testing can be conducted in minutes in an outpatient office, it may profoundly change and negatively alter their life—even though, in most cases, the testing and the results may have no apparent effect.

HELPING PATIENTS MAKE GENETIC CHOICES

In their article in this issue of *JCE,* Siminoff and colleagues highlight ways to best share genetic information with patients. But even if it were possible to be flawless in our communication with patients and families, emotions such as fear may cause fast thinking that hijacks their capacity to understand the information they receive. The delivery of genetic information may evoke the same kind of fear. And, as I have said, once evoked, a strong emotion may remain. Then, even much later, patients and family members may not want to share their genetic information with relatives for this reason. In the next two sections of this article, I will discuss patients' deciding whether they want to be genetically screened, and patients' deciding whether they want to give their genetic information to others.

Helping Patients to Decide What They Want to Know

We can screen people now to see if they will develop Huntington's disease. Many who know that they are at risk of having this disease (50 percent if they have a parent so affected) choose not to be tested.[16] This is—or should be—instructive. It suggests that some prefer not to know about their genetic risks. This awareness raises, in turn, the question of how we should proceed with all patients, since there is a complete gradient of risks of having an illness and the magnitude of those illnesses. Perhaps the chief question we might want to consider is patients' capacity to effectively use denial. When

a danger faces us, our use of denial as a defense may help save us from feelings of unremitting despair. Denial may be consciously willed and created, or it may occur unconsciously, wholly outside our control. Or it may not occur at all. It takes place in almost all of us; for example, we all know we will die, but most of us can live and focus on our daily life.

My colleague with breast cancer believes that her capacity to use denial serves her well, although she may have been able to contain her fear and enjoy her life for other reasons, such as having an optimistic outlook. Some patients may be able to use denial more effectively than others.[17] This may help them cope better when under stress, but at the same time this may have a price, as they then lack some awareness of reality. As one physician said, after she experienced devastating hardship and recognized the denial she experienced as a doctor, "Denial has its place. But when life shatters the protective walls of denial and frees the energy required to maintain them, it proves strangely liberating."[18]

Therapists seek generally to gradually help patients reduce their denial over time. Given the difference in the degree to which different people can successfully use denial, I will now pose a hypothetical case regarding what we should do when we encounter a patient who is considering whether to be screened for the earliest signs of a serious disease such as dementia. (These same concerns may arise regarding genetic screening, although to a more limited extent, and we shall consider similar ethical concerns that arise in this context subsequently.) Our hypothetical case is that of an aged patient who comes to his clinician for a routine annual check up. The patient reports he is doing fine, but has noticed some difficulties with his memory, although it hasn't affected his life. The patient may have early Alzheimer's dementia (AD) or symptoms that precede AD, or he may just have the changes that go with normal aging. The ethical question this poses is whether his clinician should do any immediate outpatient memory testing. On the one hand, the clinician may believe he or she is obligated, absolutely, as a medical professional, to test, based on the widely held first principle of "diagnose first." On the other hand, the patient's memory deficits presently don't negatively affect his life. Thus, if the clinician tests him and finds memory deficits that suggest he has early AD, it may place a dark cloud over the rest of his life, *from that moment onward*,

In this situation, the clinician may ask the patient what he would want to do. Or, better yet, the clinician may brief the patient on the question at stake, and ask, before the patient makes a decision about testing, whether he would like to discuss the pros and cons of the decision. The clinician can suggest that the patient not make a decision immediately, but think it over, ideally with his family. While the clinician may have "opened a Pandora's box" by mentioning that the patient's memory loss could be a first sign of dementia, that possibility has not been tested, and the patient could be experiencing no more than normal aging. His choice not to be tested may make it more possible for him to go on with his life, and deny it could be dementia.

Genetic testing for AD presents similar questions, even though having an AD gene contributes only slightly to later developing AD.[19] Yet, regardless of the extent of patients' risk of having an AD gene, patients may believe that they are the one person out of many who will be affected by having it, and just knowing that they have an AD gene may cause them to be significantly negatively affected. Because AD begins earlier in life than previously thought, and preventive treatments must begin early to be effective, genetic testing for AD is being done at an increasingly earlier age.[20] Genetic testing for AD is now common when much younger people volunteer to participate in research. Researchers who work with younger study participants should take into account these considerations. The fear evoked in even preliminary discussions of genetic testing could trigger fast thinking, and study participants might become less able to decide what they want.[21] Even older study participants who face making decisions about genetic testing may benefit when researchers inform them about the risks of fast thinking, and as a result be better able to make decisions.

A third example that involves making possibly difficult decisions about genetic testing—in addition to identifying an increased risk of AD in the clinic and in research—is the unearthing of so-called incidental findings.[22] These are test results that are not sought, but which nonetheless appear. When it is not clear that sharing an incidental finding will have any beneficial effect for a patient, sharing such findings is presently controversial. It is feared, on the one hand, that disclosing incidental findings may scare patients, research participants, or their family members. On the other hand, to inform them respects them maximally, even though the knowledge they receive may not be helpful to them.

An optimal approach that gives priority to respecting patients' autonomy is to ask them, when possible, what they want to do regarding incidental findings. When it is possible to ask, and patients want to discuss the findings, the discussion should not be short and ideally should be spread out over time. We might ask patients how they were able to deal with uncertain fears in the past, if they had any,

and ask them to imagine how they would feel in the future with or without the incidental findings. When patients consider how they responded to fears in the past, or how they may respond in the future, it may trigger fast thinking. We can inform patients about this risk, as it may help them to less readily accept their first, fast conclusions.

Patients Who Won't Share Genetic Information

Another difficult ethical question posed by genetic testing is how to respond when patients won't share genetic information that may be important to their biological relatives.[23] Their relatives may, for example, be at higher risk of having a disease or of being a carrier. Even if they are a carrier, they may not want to risk passing on the gene to their offspring. Generally we are precluded from informing relatives when patients don't want us to do so; usually we must respect patients' confidentiality. However, we can inform patients that even simply discussing sharing test results may evoke fast thinking. We can say that knowing about fast thinking may be beneficial to them, as it was to King Lear and the father of the Prodigal Son. If patients decide to share genetic information, who should deliver the information? There are concerns for patients who provide information and for those who receive it. We might offer to be present when patients share information and/or seek out clinicians who are knowledgeable about genetics and skilled in sharing bad news, and invite them to join the patient.

We might ask patients if it would be acceptable to tell them about some other patients we have seen. We might clarify the reason for asking, much as I did with King Lear: we are not trying to change the patients' mind, but we want to give them information that may be important to them. We can share how many patients near the end of life—or when they know they have early AD—see value in contacting a relative they once loved, even if they have lost or severed all contact for decades. These initiatives address the reality that people may value meeting and interacting with loved ones with whom they have severed ties previously, although they may not foresee this. Taking initiative to inform patients that this may be the case may prove most beneficial to them. Patients may talk about a relative they once loved, like a sibling or cousin with whom they enjoyed fishing. If this is the case, we can ask if they have any interest in our trying, on their behalf, to see if we can help them reunite—to say hello once again, while they still can. We can say that the results sometimes are close to miraculous—because they are. Patients often are able to reunite and are glad that they did.

We can share this with patients who are trying to decide whether to give relatives genetic information. We might first explain the likely effect of their having such a discussion with us—namely, that it may trigger fast thinking. It might also stir up a resentment they felt long ago. If we say this, it may become a cue for fast thinking. This is called the "bandwagon effect": presenting information about what others do can increase pressure on us to do likewise, and this pressure can trigger fast thinking. Doing this, then, is mildly coercive. To offset this effect, we can explicitly acknowledge its coercive effect. We can inform patients that this is an additional cue that may trigger fast thinking, and it, too, may decrease their capacity to soundly reason in regard to whether they are willing to share with relatives important information about their genes.

Fast Thinking Can Influence Policy Makers

In regard to genetics, many policies are open to question—at the least. A policy considered above is whether to respect a patient's confidentiality when, as a result, another may be harmed. Some particularly contested policies regarding genetics were designed primarily to protect children. One such policy is parents shouldn't have access to genetic information about their child unless the child would benefit medically, during childhood.[24] A second is that children should not have access to information about their own genes until they can decide whether they want the information as an adult.[25] A third is that parents should not receive genetic information regarding a child's paternity.[26]

Policies intended to protect children may be the result of value priorities that were influenced by fast thinking, or slow thinking that was mistaken. This may be especially likely because we have such strong feelings about children and about protecting them. As Kahneman says, "Anyone can understand and sympathize with the reluctance of parents to trade even a minute increase of risk to their child for money."[27] These three policies may be the best possible, but each may have been affected by fast thinking. Some policies enacted in the past to protect children prevented the conduct of research needed now to treat them. We shall look at three policies briefly. Since the policies were intended to protect children, these examples particularly exemplify decisions that may reflect fast thinking. The following are some brief thoughts and questions.

Not Being Able to Know about a Child's Genes. When parents know about a genetic illness that their child may or will experience as an adult, they may be better able to help their child be prepared.[28] This is possible because parents may be able to love the

child just as he or she is, and the child may internalize this love and become maximally resilient. When parents unconditionally love their child, the child may adopt the same highest regard for him- or herself and so become "immunized" to stresses caused by to genetic illness as an adult.

Here is an example of the kind of unconditional regard I mean. Some of my patients feel depressed because they lack an ability others have. If the patient is a parent, I ask how the patient would feel if their child was the worst player on a sports team. I ask the parent, would he or she be more proud of the child if the child was the best player on the team than if the child was the worst player? The patients uniformly and instantly respond, "No! I would be prouder if my child was the *worst* player, because then my child would have the courage to keep playing under those circumstances." I then ask, "Why is it that you can't apply this same critical insight to yourself?" Sometimes this seems like an epiphany. Parents do not value the child for what the child can *do,* but rather who the child *is.* This exemplifies the unconditional regard that helps children become resilient. Many of us were fortunate to have parents who could greatly soothe us. As we go on and age, that memory may be a source of resilience. We know that we can be soothed, and we know we can do this for ourselves.

Giving a Child Genetic Information. Another policy is to not give children information about a genetic condition that may not affect them until they grow up. It could be argued that parents can handle this information, but children cannot. This argument may reflect unrecognized biased, fast thinking, because actually, parents and children might gain a great deal from having and sharing this knowledge together. I think particularly of families who have a child with cystic fibrosis (CF).[29] These parents may care so greatly for their child that they provide a quality of life equal to or surpasses that of many children. These parents and children may have such joy in their lives that parents who have one child with CF may choose to risk having another. These parents may see themselves as their child's ally. This exceptional commitment may be necessary should the child decide the time has come to die. Only with the parents' pressure may the child's clinician allow it.[30] Further, parents who know their child may have a genetic illness when the child grows up, and who talk with their child about it, may help the child prepare for this possible later experience.[31]

Disclosing Nonpaternity. What of the present policy to not give parents information that "may indicate" nonpaternity? I place "may indicate" in quotes because this is what some clinicians say, in an effort to allow parents to believe, in spite of genetic testing, that the father is his child's biological parent. This is always possible, and may be most critical to some. It is all-important that we, in every way possible, seek to convey to parents that they can parent as fully and richly as possible whether they are or are not a child's biological parent.

Would a change in our nonpaternity policy affect this approach? Probably not. Yet this is a change we surely should try to promote in other ways. Here, fast thinking may further two opposite ends. We know how nonpaternity revelations may affect some families. It may destroy them. This may move us—as our desire to protect children does—to keep the policy we have. A second response is more instructive. Some people believe strongly that we should divulge nonpaternity because, as they may put it, the mother has "made her own bed." This "fast belief" smacks of contempt and exemplifies the worst kind of outcome that fast thinking can bring about. These policies may be as they should be, but, regardless, whether they reflect fast thinking is a question we should ask. When making policy, fast thinking outside our awareness may skew our options and lead to suboptimal decisions we may later regret.

FAMILIES IN THE ICU

In their article, Siminoff and colleagues suggest the approaches they share will be useful to those who experience stress, for example, in an ICU. I will expand on this. I will address ways in which we might best reduce the stress that family members feel, and the fast thinking that may result from it, that may impair the decisions they make in an ICU.[32]

What Is Most Important to Families?

An ideal way to help to reduce family members' fast thinking is to ask them what they fear most. This has been studied. One study reports families' three main concerns: clinicians will abandon the patient, and them; clinicians will allow the patient to suffer; and clinicians will go against what the family wants. The last is the hardest to consistently address. I will suggest several approaches that may reduce the risks of fast thinking in the ICU. I will discuss them in order, from the time a patient enters the ICU until he or she may be near death. I will focus on less-common steps to help families that may reduce their primary fears to the greatest extent possible.

Approaches to Reduce Families' Fast Thinking

Indicate Why "We" Are Meeting. When we first convene any special kind of meeting, family members may fear bad news, and this may trigger their

fast thinking. Family members may fear, for example, that we are about to tell them that the patient has taken a turn for the worse—or, worse still, we are about to tell them we will do something they don't want. This apprehension is particularly likely if, in the past, clinicians have always talked with them only informally and when they were "on the run."

Consequently, our first task when we call for a special meeting is to try to reduce family members' fast thinking by saying why we will be meeting, before anything else. We should reassure the family, if we can, and if it is true, that we will meet because, in the ICU, such meetings are routine, and this is so because the illnesses of patients in the ICU are more serious. (If this is never the case, because there are no routine meetings, staff might want to consider instituting routine meetings, so that someone on staff meets with each patient's family members on a regular basis.) In one neonatal ICU, for instance, a nurse makes herself seen and available on an ongoing basis. She does this so that parents can get to know her, and thus and more easily approach her if they feel the need. A profound gain from doing this, in spite of the greater expense, is that parents may seek out this nurse when they merely *feel* they have the need, whether or not it turns out that their need was, on whatever scale used, justified or valid.[33]

When We Will Not Do What the Family Wants. The greatest fear of family members is that we will go against what they want.[34] We can inform them that we will do our best to make choices *together.* We can further say we will do our best to tell them when that is not possible, and make every effort to explain why and talk it through with them. For example, a hospital may have a futility policy that allows staff to not give a patient a treatment that they believe is futile. By pointing out this policy early on, before any such condition arises, we can be crystal clear that we are sharing this with the family to maximally inform them, not because we are in an instance of such futility. Paradoxically, doing this may increase the family's feelings of trust, and possibly help them later, should these circumstances arise. When we provide this information ahead of time, we can say *why* we are saying it when we are. We can say we are aware that, for many families, this is their chief fear and concern. We can hopefully offset any likely ill-effect by telling the family that we want to reassure them by sharing the criteria we will use when we work with them. This may seem too radical an approach, but it is worth considering the situation from the family's "shoes."

An optimal way to help patients and families may be to urge them to imagine there are three persons who are always at the bedside: one is a clinician, expert on the patient's medical condition; one is an ethicist, able to see whether any values are being missed; one is a lawyer, who can ensure that patients and families are able to pursue all of the options to which they are legally entitled. These three persons can help patients and families accomplish two important goals: to give patients every treatment to which they are entitled, and to ensure that patients are treated equally and have good treatment, whether they are rich or poor.

We may wish to explicitly tell families that these goals are most important to us. We can add that we say this because, if they believe for a moment that the patient is receiving suboptimal medical care, suboptimal ethical care, or not having some option to which they believe the patient is legally entitled, they should tell us. We can say that we will seek out experts to address their doubts as best we can.

Give Families 24/7 Access to Knowledge. To address families' fears that we may abandon their loved one, and them, we can say that we will not abandon them, using other words, and act to exemplify this.[35] Perhaps the best way is to arrange for someone *who knows specifics about the patient* to be available around the clock. This requires adequate and additional briefing. Its cost should be more than offset by the practical and humane gains it confers. We may go beyond this. Families' fears of being abandoned may be fueled by the increased isolation they feel as a result of having lost contact with prior clinicians.[36] Thus, in the ICU we can, and should, find a way to offer to contact previous clinicians, and fill them in on the patients' condition, so that families can discuss their decisions with prior clinicians, if this is what they want. And there is an attitude that we may seek to have that may be even more important.[37] We may have to have this attitude if families are not to feel abandoned: rather than feel we must fight death during our shift, we could feel that, if death occurs, we *want* it to happen on our shift. Why? Because then we could be *with* patients and families when this occurs, with them emotionally, as patients pass on from this life. This attitude is manifested by hospice workers, who hope, rather than fear, that their patients will die on their shift so that they can have what they see is the greatest privilege, of being with patients and families at this time. An easier way to reduce families' fear of abandonment is to acquire the habit of listening more than we speak. Research indicates that families are much more satisfied when they can talk about what they feel and think than when they only listen. We tend not to see this. There is evidence that even when clinicians talk much more than families do, and families report they felt that clinicians cut them off,

many clinicians rate their interactions with families as the best that could possibly be achieved.[38]

Share Clinical Uncertainty. We should soothe families even when we feel uncertain. We may feel it is best to hide differing views and conflicts among staff because it is necessary to reduce family members' fears. But it is much more likely that we can reduce their fears by sharing our own feelings of uncertainty, and, as we strive to be "with" patients as they die, to bear our fears about uncertainty together. At the last annual meeting of the American Society for Bioethics and Humanities (ASBH), there was a pre-meeting course to help clinicians become more at ease with uncertainty. This approach had been carried out with clinicians at Harvard, and follow-up studies indicate the participants in the program changed: they became more at ease with uncertainty. The program involved looking at art, in groups.[39] The different interpretations of art that clinicians experienced helped them to newly tolerate differences in viewpoints that could not be resolved. Clinicians who are comfortable with uncertainty may be able to convey this to patients and families by what they say and how they conduct themselves.

Share Frightening Prognoses. We can reduce family members' fast thinking, even when telling them bad news about the patient's likely demise.[40] Some patients have a medical condition that makes it particularly likely, under certain circumstances, that they will die. Their family should know this. And we should tell them. Examples are congestive heart failure and chronic obstructive pulmonary disease. When patients have one of these conditions, their course typically waxes and wanes. If this happens many times, and each time patients recover, family members may be lulled into believing that when this occurs in the future, the patients will again recover. We should tell these families, however, this may well not be the case. The family may be much more afraid, but will be more prepared. In addition to this gain, families may see how far we will go to show the greatest care for them. Thus, in the short run, this may hurt them, but in the longer run it may increase their trust and reduce their fear.

Ask Families if Patients Are Suffering. Perhaps the best way we can help to assure that family members know that we will not let patients suffer is to *encourage* them to come to us *whenever* they fear patients are experiencing physical or emotional pain. All too often the opposite is the case. We are busy. We can give families a reason we want them to do this: they are likely to be with patients much more and so will be much more likely to see signs of distress. We can do even more: relieve what families may see as distress when it does not harm the patient. Some clinicians, for example, give medications to reduce a patient's fluid load when there are gurgling sounds coming from the patient's throat that the family sees as evidence the patient feels air hunger, as if the patient is suffocating. Some clinicians may, at the other extreme, give a patient intravenous fluids when the patient's skin in dry, and family members believe the patient is parched and thirsty.

What is remarkable about these examples is that they represent the extent to which some clinicians will depart from the often-voiced principle that only the patient's good should always, absolutely prevail and never be compromised by others' interests, including those of their family. At the most recent meeting of the ASBH, two presentations especially carved out conditions when families' interests should be assigned moral weight.[41] Increased commitment to families' interests, when what patients want or need is little affected, is supported by this underlying rationale: it may be what the vast majority of patients would want if they were asked.

Help Families Decide What to Say at the End of Life

As the death of a loved one comes near, we may reduce the stress and fast thinking experienced by family members by taking the initiative to give them guidance in what they may say to the patient. Four thoughts are well known and have been shared over time: "I love you." "Thank you." "Please forgive me." "I forgive you." A fifth thought we could suggest is less well known: family members may tell their loved one that although they will feel extreme sadness at the loved one's death, they know for sure that they will be able to carry on well, afterward. Family members may want to say this, we can add—speaking once again to the "why"—because many patients, as they die, may, more than anything, fear that their family will not be able to carry on well after their death. We can discuss this with family members. We can say that they may worry that saying they will be okay may risk communicating to the patient, wrongly, that they don't really care. Anticipating this concern, we can address it. If family members remain concerned, we can say what we ourselves do with our patients, and why. We can give them, as I've said before, our *reasons*.

With this information, family members will be able, as they talk with their dying loved one, to say that they fear the patient may take what they are about to say the wrong way, but they do not know how to say what they want to say in a way that avoids this. This should reassure the patient, and may relieve the patient of what may be his or her greatest fear—that family members may not be able to get along well after the patient dies. The patient may

not know whether family members will be able to get along well, but may gain some faith from the fact that family members say they can. Family members have had the courage to say this, even though they know that the patient could take it the wrong way. We can also tell family members about *this*.

When family members communicate their concerns with their loved one, they may feel great apprehension they might "get it wrong." We may, accordingly, reassure them that if they take the risk of sharing this important information with their loved one, they should take special care later to not feel regret. At all costs, they should feel good they did the best they could. What they said, we can remind them, no matter how they said it, will have gone an extremely long way.

CONCLUSION

In this issue of *JCE,* Siminoff and colleagues describe how clinicians can help patients better understand the donation of genetic tissue and the information they receive in stressful settings such as the ICU. I presented other factors that may rob families of their capacity to understand, even when we communicate optimally. I used Kahneman's concepts of fast and slow thinking and focussed particularly on how fast thinking may bias our reasoning when we are under stress. I discussed this generally and in regard to genetic testing and policies regarding genetic testing, and in regard to the families in the ICU. There is, though, an implicit distortion noted at the beginning of this article: in concentrating on the harms of emotionally driven fast thinking, I have ignored the immense gains that emotions and fast thinking can make possible.[42]

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Features

"Buying-In" and "Cashing-Out": Patients' Experience and the Refusal of Life-Prolonging Treatment

Nathan Scheiner and Joan Liaschenko

ABSTRACT

Surgical "buy-in" is an "informal contract between surgeon and patient in which the patient not only consents to the operative procedure but commits to the post-operative surgical care anticipated by the surgeon."[1] Surgeons routinely assume that patients wish to undergo treatment for operative complications so that the overall treatment course is "successful," as in the treatment of a post-operative infection. This article examines occasions when patients buy-in to a treatment course that carries risk of complication, yet refuse treatment when complications arise. We coin this counter-phenomenon "cashing-out." Cashing-out may elicit negative feelings among careproviders. We question why patients or families may wish to cash-out. One reason may be the changing epistemological position of patients as they experience a complication. The shift from the hypothetical discussion of complications during the initial informed-consent process to the experience of having a complication represents new knowledge. Patients and families may use this knowledge as the basis to revoke consent for some or all of the remaining treatment course. This article seeks to understand cashing-out in terms of the patients' experiences. We hope to prompt recognition of this phenomenon across medical contexts and to provide impetus for further work to understand why patients may wish to cash-out.

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INTRODUCTION

Patients occasionally consent to surgical or medical treatment yet refuse care when complications of the primary treatment arise. This may lead to conflict among patients, family members, and clinicians. This conflict is best understood through Schwarze and colleagues' observation of surgical "buy-in," an implicit understanding many surgeons hold that when patients consent to surgery, they consent to both the procedure and any follow-up care the surgeons anticipate.[2] We term the unanticipated refusal of medical care for a complication of treatment by patients or their advocates "cashing-out." We illustrate the concept by examining the complicated case of a patient who underwent liver transplantation.

CASE

A middle-age family physician became cognitively impaired from central pontine myelinolysis (CPM—a neurological disorder characterized by damage to the brain stem, which may result in changes to mental status, acute paralysis, difficulty swallowing, or speaking) one month after receiving

a liver transplant. The patient was also bacteremic and had possibly aspirated. The transplant team recommended aggressive antibiotic treatment and endotracheal intubation to the family. Neurology consultants wrote that the patient's CPM might resolve over weeks to months, and that, if it did resolve, it would require intense physical therapy without guarantee of return to baseline function.

This patient had do-not-resuscitate/do-not-intubate (DNR/DNI) orders prior to transplantation. These had been suspended for the procedure and had not been re-ordered. The patient's family, which consisted of the physician's spouse and three adult children—one of whom was a nurse and the spokesperson for the group—doubted the wisdom of intubation to treat aspiration pneumonia given the patient's grave, unanticipated, and uncertain neurologic condition. Citing the patient's values and advance directive, they requested the reinstatement of the DNR/DNI orders, which was done.

The transplant team disagreed with the family. The DNR/DNI orders were revoked by the treatment team, and clinical ethics was consulted after the family requested DNR/DNI orders once again. The DNR/DNI statuses were reinstated after a family conference determined that this was in accordance with the patient's advance directive, which stated that he wished to refuse aggressive care—including resuscitation and intubation—if it was "reasonably certain" he would not recover his ability to know who he was. The patient was made comfort-care-only, and his antirejection medications were stopped.

The transplant team had several strong reactions to this limitation of care, which they reported to the authors: "Transplant patients are considered 'full code' for a year" regardless of earlier DNR/DNI orders. Maintaining full-code status "would be difficult to enforce, though we talk about it behind closed doors." The patient had an obligation to the donor: "someone died so they could live." The staff has an obligation to the system: "We have to protect the organ." One reason that treatment should continue is that "survival is measured at one year." The patient reported to the authors that the transplant team told him: "I don't like those [advance] directives," and "you never would have gotten this liver—it's way too valuable. . . ."

Two days later, the patient spontaneously became alert and oriented to his medical condition. He stated that he wished to restart antirejection medications and would agree to one week of intubation and ventilator-assisted respiration should it become necessary. The next day he shortened his prospective consent to ventilation to two days. His DNR status was retained. He repeatedly said that his physicians should withdraw his care if it became clear that treatment would no longer allow him to interact with his grandchildren.

Understanding Surgeons' Expectations and Cashing-Out

This disagreement may be best understood using the concept of "surgical buy-in." Surgical buy-in is defined as "an informal contract between surgeon and patient in which the patient not only consents to the operative procedure, but commits to the post-operative surgical care anticipated by the surgeon."[3] A recent survey suggests that up to 62 percent of surgeons across surgical subspecialties would create such an informal contract with patients.[4] Patients may buy-in to post-surgical treatment because they understand that some surgeries may have grave, but reversible, complications. Patients also trust their surgeons to decide on clinical decisions that are in accordance with their quality-of-life values.[5]

However, how such contracts are created and their form are unclear. These agreements often go undocumented in the medical record, and the degree to which surgeons expect buy-in to post-operative treatment depends heavily on several factors, including surgeons' belief in the acceptability of withdrawing life-sustaining treatment within the first two weeks of a major surgery, the degree of surgical risk, and whether morbidity and mortality outcomes must be reported.[6] Of the surgeons surveyed, 60 percent said that they would sometimes or always refuse to operate if a patient expressed preferences to limit life-supportive treatments such as mechanical ventilation or dialysis in the post-operative period.[7]

Furthermore, patients express a wide variety of preferences regarding the degree to which they are willing to give up decision-making authority in the post-operative period. In a recent survey, Nabozny and colleagues found that patients' preferences for autonomy in the peri-operative period exist over a wide range.[8] Some patients believe that decisions to correct peri-operative complications are matters of technical, not moral, expertise to be determined by physicians. Others believe such decisions should be made based on advance directives or by healthcare agents. Importantly, the majority of patients surveyed reported they had no explicit discussions about the limits of life-sustaining treatment in the case of major, life-changing complications with burdensome corrective interventions.

Our experience reflects the concern expressed by Schwarze and colleagues that patients may find

the burdens of life-supportive treatment to outweigh the benefits, and that informally contracting the limits of post-operative treatment may be overly paternalistic. In such instances, patients or their families may wish to refuse treatments. We term this refusal "cashing-out": the expressed refusal of medical or surgical treatment, in response to a change in values or medical status, when an agreement to continue treatment was previously understood to exist. We believe explicit recognition of this phenomenon is important because it highlights both the ethical question of what precisely patients consent to when agreeing to surgical procedures, and the practical concern that cashing-out can elicit "feelings of betrayal, unhappiness, disappointment, and even culpability" among careproviders,[9] possibly to the detriment of their relationship with patients.

Ways of Knowing and Cashing-Out

One of several ways to understand cashing-out is through focus on the embodied experience of patients as their illness develops. One aspect of informed consent regards the knowing of medical facts related to oneself and one's treatment options, then deciding which option best aligns with one's values. The body is central to knowing one's status in the world. Knowing one's status in the world is achieved through sensory perception: sight, hearing, touch, olfaction, and gustation.

The embodied way of knowing is important because it concerns first-person knowledge, which is to say "people have first-personal access to some of their bodily states, yielding direct knowledge . . . about what it is like to be in those states."[10] Personal experience is rich or "thick" with the sensations of daily life, and interpretation or judgment of events depends on how sensations are filtered through values and emotions. First-person knowing can be contrasted with third-person knowing, the primary method by which we construct the experience of others via imagination, interpretation of externalized signs, or listening to their narrative.

We maintain that patients may cash-out on a first-person, or embodied, basis as a matter of their changing epistemological position. Direct knowledge of what it is like to be sick may be why patients elect to forgo treatment for post-surgical complications. Although possible complications may be explained in great detail in the process of informed consent, we believe patients cannot have direct knowledge of these experiences unless they have experienced these complications previously. Patients may be able to imagine the experience of a complication, but this does not translate to embodied knowing of the experience. For example, most people have embodied knowledge of the experience of nausea from routine illnesses, but can only imagine the experience of nausea secondary to chemotherapy. Yet even embodied knowledge of a potential complication may not prevent cashing-out, since values may change over time, and a recurrent complication may be judged intolerable the second or third time around.

The first-person perspective may account for the difference between having a disease and experiencing illness. Disease may be taken to mean those physical changes that lead to systemic dysfunction.[11] It is "an organic phenomenon (physiological events) independent of subjective experience and social conventions."[12] Whereas "disease" is objective, "illness" is subjective. It is "a situation where a person's 'being-in-the-world'[13] is characterized by that lack of the rhythm, balance, and tune of everyday living that characterizes not 'being-at-home.' "[14] More simply, illness is a disruption of the flow of one's daily life. Patients may become accustomed to living with a disease in a certain rhythm, balance, and tune in their life, and experience an acceptable quality of life. However, a complication or a corrective medical or surgical procedure may disrupt that pattern of living, and introduce a new illness. This new set of embodied sensations, filtered through patients' goals and values, may be the basis for patients' cashing-out.

Of course, in this case, the patient's family members refused treatments on the patient's behalf. Following the feminist recognition that social situation is important to the formation of knowledge,[15] we argue that families have an additional way of knowing the life and values of others. We informally term this "third-person-intimate" knowing, which is based on the observation that "People behave differently towards others, and others interpret their behavior differently, depending on their personal relationships. . . ."[16] Families have particular knowledge of members' lives and values as a matter of the intimate relationships they maintain with one another. They simultaneously construct and hold the identities of individual members, as well as define and instill values as a family unit, among other functions, throughout life.[17] This makes family members particularly well suited to describing the values and preferences of patients.

Refusal of treatment by family members is sometimes a substituted judgment on the basis of explicit conversations they have had with the patient. However, families often acknowledge they have not had explicit conversations regarding specific interven-

tions, or even the patient's values regarding end-of-life care. In these instances, families often make statements such as, "I just know he would not want this." Although the basis for the refusal by this patient's family may not be as strong as a first-personal refusal or substituted judgment, an ambiguously defined refusal of treatment by a family member should be taken as greater than simple guesswork. On the basis of the above feminist and experiential considerations, a refusal by a family member likely represents an understanding of the "textured life" of the patient's normal rhythm, balance, and tune of being-in-the-world, which are defined by the patient's normal behaviors and values.

The third-person viewpoint of the clinician is not based on an intimate understanding of the daily life of patients and their values, as clinicians rarely see patients leading their normal lives. Instead, the clinical viewpoint is based on an understanding of anatomy, physiology, pathology, and prognosis, which is, in turn, based on a clinician's experience of disease as it is located within the bounds of patients' bodies. It is a disembodied way of knowing. To be clear, we do not mean to imply that the clinical viewpoint is without value: after all, patients seek out the clinical viewpoint precisely because they desire recommendations for medical treatment. However, defining the limitations of the clinician's viewpoint in medical decision making brings into relief the conflict of first-person and third-person experiences. It offers an explanation of why ethical and practical problems arise when patients cash-out, even when clinicians are tempted to say, "Just stick through this with me, I promise I can get you feeling good again."

Implications

There are many ethical facets to this case. Readers will note we have not addressed the complex notions of the assignment of responsibility and obligation, the clash between autonomy and justice, and the potential conflict of interest that were introduced by the transplant team as they made objections. This is because we wish to focus on the clinical question at hand, as opposed to grand questions of rights, duties, and principles. How will we proceed now that we have met an impasse of values regarding whether a patient has prospectively consented to the treatment of post-operative complications?

First, in our experience, while analysis of ethical principles can occasionally provide a resolution to a conflict between clinician and patient, there are many times in which it will not be useful. In this case, the analysis of principles will ultimately lead us to systemic versus individualistic concerns. This is to consider whether the demands of justice to the organ sharing system will trump the individual right of the patient to decide what treatments are acceptable. Such considerations are not useful in resolving the conflict in this case because there are perfectly good reasons to prioritize either systemic or individual concerns. These may simply be meta-ethical preferences. Additionally, such a consideration of principles often pits stakeholders against one another, losing sight of the common understanding that all involved are working towards their understanding of the most acceptable outcome for this particular patient.

Second, a focus on the analysis of principles unnecessarily restricts our discussion to the particular ethical problems of transplantation. This case rings true because we ask patients to buy-in to many kinds of burdensome medical treatments, not just surgical treatments. Consequently, cashing-out occurs in many sorts of medical decision making, from the post-surgical patient experiencing a complication to the patient who decides to stop taking a medication due to intolerable side-effects. Clinical ethics consultants should be aware that while formal discussion of buying-in within the literature has focused on the surgical context, we suspect they will find it in all aspects of medical care.

That the patient awoke to consent to a short trial of intubation in this case is a *deus ex machina*. In many instances patients do not awaken to voice their consent or refusal, or, if they do, then they often lack full capacity to decide such monumental questions. These circumstances are tragic for all involved, particularly families who are asked to make difficult decisions regarding the life of their loved one. We believe that when an impasse of values is reached with a patient or family members in circumstances such as this, the practical question of how to proceed can be reframed based on the patient's experience. Then, patients and family members become best suited to determine what treatments are acceptable. We are committed to this position because it is ultimately patients and their families who will have to bear the burden (or benefit) of continuing treatment for post-procedural complications.

Clinical ethicists might proceed in consultations such as this one by asking what has changed, in values or medical facts, and how the patient or family is experiencing that change. Shocking statements made by the clinical team might prompt ethicists to ask about the clinicians' expectations and experiences as well. Interpreting the values of both pa-

tient and careprovider can help consultants build empathy among all stakeholders. Explicitly acknowledging feelings of frustration and bewilderment may help balance the emotional tenor on all sides of a disagreement. Furthermore, building a narrative of the patient's illness, as a story of changing facts and understandings, can help shepherd the patient, the family, and the clinical team to the most acceptable conclusion of the story, whether treatment is continued or not.

Finally, we will pose a question to prompt further conversation and research: When and why do patients wish to end an informal contract such as the surgical buy-in? We have suggested that one possible reason is when the embodied experience of the procedure or complication becomes too much to bear. Empiric work to determine patients' and careproviders' values surrounding this phenomenon should clearly be undertaken. We hope this case provides impetus for further work to better understand the phenomenon of cashing-out.

CONFLICT OF INTEREST, PRIVACY, AND INFORMED CONSENT

The authors have no conflicts of interest to disclose. The names, ages, and genders of all of the individuals involved in this case have been altered to protect their privacy. Only the details essential to the patient's medical condition and the narrative of this case as it unfolded have been included. All statements in the case were made directly to the authors, except for those specifically noted to have been told to the patient and reported to the authors by the patient. The patient provided written informed consent to publish this case.

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Impact of Cognitive Load on Family Decision Makers' Recall and Understanding of Donation Requests for the Genotype-Tissue Expression (GTEx) Project

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ABSTRACT

Genomic research projects that collect tissues from deceased organ and tissue donors must obtain the authorization of family decision makers under difficult circumstances that may affect the authorization process. Using a quasi-experimental design, the Ethical, Legal, and Social Issues (ELSI) substudy of the Genotype-Tissue Expression (GTEx) project compared the recall and understanding of the donation authorization process of two groups: family members who had authorized donation of tissues to the GTEx project (the comparison group) and family members who had authorized organ and tissue donations in years previous, who subsequently participated in two different mock-authorization processes that mimicked the GTEx authorization process (the intervention groups). Participants in the comparison and intervention groups were matched on key demographic characteristics.

We found that participants in the intervention groups who experienced a mock-authorization process demonstrated better

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recall of the tissue donation request than members of the comparison group. Our data indicate that the stress associated with the loss of a loved one limited the ability of family members to recall details about the GTEx project. However, we found a similar lack of knowledge in both the comparison and the intervention group participants, suggesting lack of knowledge may be due to the complexity and unfamiliarity of the information presented to them during the authorization process. We discuss these findings in the context of everyday clinical decision making in cognitively challenging conditions.

INTRODUCTION

The need for high-quality genomic data for medical research is growing.[1] A potentially plenteous source of the human material needed to support genomic research is through the generous donation of tissues from newly deceased patients by their family decision makers (FDM). The Genotype-Tissue Expression (GTEx) project is a leading-edge biobanking and genomic research project that provides high-quality gene expression data to study its impact on common diseases, that has successfully secured donations from the grieving FDMs of 961 deceased donors.[2] This mirrors the efforts of the National Institutes of Health's (NIH's) Precision Medicine Initiative (PMI) with living donors, as GTEx collects not only tissues but also links deceased donors' medical records and genomic information.

The Ethical, Legal and Social Issues (ELSI) study, which is a part of the GTEx project, has been pioneering best practices in requesting tissue samples and examining challenges to ensuring that these requests are conducted with sensitivity and in a manner that supports informed decisions about participation in GTEx.

The GTEx authorization process presented complex information about biobanking, genetic research, and confidentiality to FDMs after an initial conversation with them about donating the organs and or tissues of a deceased family member for transplantation.[3] The information was verbally delivered using a relatively brief script. Our initial pilot work with FDMs found that 29 percent of the families who were asked to donate to GTEx failed to remember that they were asked to donate for research, and 40 percent incorrectly believed that they would receive the results of the genetic tests.[4] Other studies of living donors have found similarly profound decrements in understanding and recall.[5]

Ensuring that FDMs understand the essential information needed to authorize the donation of organs and tissue—or of informed consent in the case of living donors—is especially salient in light of the growing need for increased participation in genomic research. For instance, NIH's groundbreaking PMI project will likely catapult the practice of precisely tailoring medical treatments to a patient's genomic profile through the participation of one million patients.[6] Additionally, the expansion of "personalized" medicine requires sustained investment in next-generation genomic and RNA (ribonucleic acid) sequencing projects that discover targeted disease treatments.[7]

Efforts to advance genomic profiling, with the goal of changing medical care, highlight the documented incongruence between the complexity of the information required to make an informed decision and the low levels of knowledge that have been observed in the general public. Asking individuals to participate in what may be an initiative that lays open their genomic information requires that we provide them with a higher level of education and information. This may entail using different and ongoing education and contact with the individuals that are well above our usual and common practice. Since the original President's Commission on Protection of Human Subjects published its *Reports of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research,* bioethicists have urged researchers to view obtaining subjects' informed consent not as a singular event in time, but as an ongoing process.[8] Especially in clinical research, most patients will participate in a study for months, and even sometimes years. Thus, obtaining ongoing consent could include checking in with patients periodically to discuss their trial participation experience and to affirm their willingness to continue their treatment within the context of the trial.

Despite these recommendations, informed consent continues to largely be practiced as a one-time-only event. While informed consent is not applicable in the context of requesting organ and tissue donation from a deceased individual, this study examined how the complexity of the information presented during the authorization process affects individuals' recall, and the implications for informed participation in modern genomic studies.

Factors Involved in Recall and Understanding

Cognitive Load Theory (CLT) offers potential insight into the problem of participants' recall and understanding.[9] CLT purports three dimensions of mental load: the complexity of the information (that is, *intrinsic load*), the complexity of the presentation of the information (that is, *extraneous load*), and the complexity of the schemas developed while

processing the information (that is, *germane load*).[10] The total burden imposed on decision making (that is, cognitive load) is comprised of the sum total of the mental load and the mental effort or attention given to the information that is presented. We posit that the combined effects of heightened emotions, exhaustion, extreme stress, and the volume of information that FDMs receive about organ and tissue donation, for both transplantation and research purposes, impedes their ability to process the information they receive, and their subsequent recall and understanding of the study's details.

In the case of the GTEx project, the highly technical genomic and medical research concepts presented to FDMs represented intrinsic load. Extraneous load was increased through the verbatim reading of an authorization document used to disclose the elements of informed consent regarding participation in the project. The intrinsic and extraneous load, in combination with the FDMs' already heightened emotions, impaired FDMs' ability to process information (germane load). This, in turn, resulted in compromised recall and comprehension of the information provided.

To better understand the processes involved, we employed a novel study design that manipulated the GTEx request environment to assess the degree to which the stress and grief associated with the death of a family member impacted cognition. Specifically, we compared FDMs' recall and understanding of a GTEx request for donation between two groups. The first—the comparison group—was comprised of FDMs who were asked to donate the patient's tissues to GTEx when they authorized the donation of the patient's solid organs. The GTEx requestors used a standard authorization script with this group.

The second group—the intervention group—was comprised of FDMs who experienced a simulated request for GTEx donation years after they experienced a request for solid organ donation. The intervention group was further split into two groups: the direct intervention group and the enhanced intervention group. For these two groups, the requestors used two different authorization processes (see figure 1); one of the processes replicated the request as received by the comparison groups and the other used an enhanced process.

The FDMs in the two intervention groups differed from the FDMs in the comparison group in that the FDMs in the intervention groups were not acutely grieving the loss of the patient, having experienced the donation request up to four years prior. On the other hand, the members of the intervention groups were highly comparable to the members of the comparison group, as they all had similar experiences of donation for transplantation. Members of the intervention group had the prior experience of making a donation decision that they could use as a framework for their experience with the hypothetical GTEx approach presented to them.

We were not primarily interested in the intervention groups' decisions to donate, as research indicates that decisions made in hypothetical scenarios may be affected by *hypothetical bias,* wherein participants overstate their valuations, their intention to act cooperatively, and their plans to act, as compared to their actual behavior in a real life context.[11] In this study, by removing the heightened emotional state of the members of the intervention groups, we were able to test whether grief and stress,

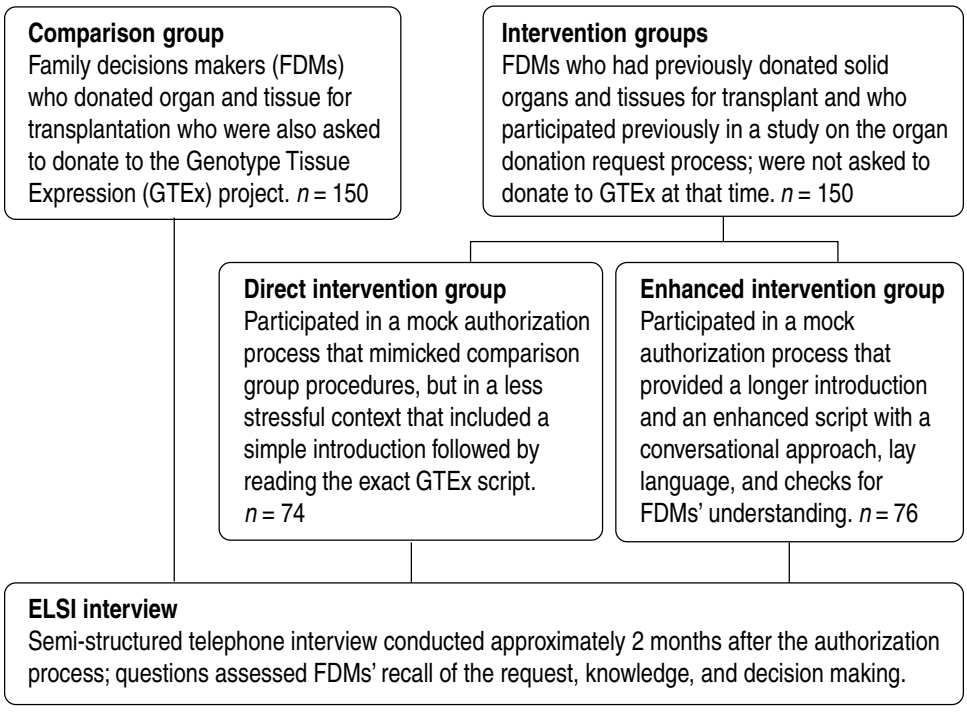

FIGURE 1.

versus the complexity of the information presented, were most highly associated with participants' recall and knowledge. We hypothesized that members of the comparison group, who received the standard GTEx request, would have worse recall and understanding than members of the intervention groups.

METHODS

GTEx Authorization Environment

The National Disease Research Interchange (NDRI) coordinated GTEx tissue collection activities and provided the ELSI team access to the contact information of all FDMs who were approached about the option of GTEx participation at five of the project's six geographically dispersed Organ Procurement Organizations (OPOs). Request staff were trained by NDRI and their OPO employers to approach FDMs about the option of donating to GTEx and to discuss aspects of tissue donation for research. A brochure explaining the purpose of the GTEx project and the extent and nature of participation were provided to participants who were approached in person. Requests made to FDMs for patients who were not eligible to donate solid organs for transplantation, but possibly to donate tissues, were made by telephone; these FDMs received a copy of the authorization form and, depending on its availability, the GTEx brochure. FDMs who authorized donation also agreed to the release of the patient's medical and social history records, various tissue samples, and, when medically suitable, the whole brain to GTEx. At the time of authorization, FDMs provided blanket authorization for unspecified future research and agreed to the sharing of aggregate data via the internet to NIH-registered researchers.[12]

Procedures

This study employed a nonrandomized quasi-experimental design with matched comparisons to determine whether FDMs' recall and understanding were affected either by the stressful *environment* in which GTEx requests were made or the *manner* in which the requests were made. OPOs made requests for GTEx to FDMs after they were asked to donate solid organs and tissue for transplantation. Organ donors and their families represent only a small subset of the population in the United States (it is estimated that only 1 to 2 percent of deaths in the U.S. are eligible to donate organs for transplantation).[13] To obtain a relevant intervention group, we randomly sampled from a cohort of families of organ donors who had participated in a previous study of the transplantation donation request process. These FDMs made organ donation decisions three to four years prior to the current investigation.[14] A matched comparison group was drawn from organ donor families who had been asked to donate tissues to GTEx subsequent to their decision to donate organs for transplantation. Thus, all participants had the same experience of being asked to donate a family member's organs. The comparison group had the additional experience of being asked to donate tissue for research to GTEx. The relevant difference between the comparison group and the intervention groups was the participants' environment during the GTEx request. Members of the intervention groups heard the GTEx request via a simulation delivered three to four years after they experienced a request for donation, and the comparison group received the GTEx request immediately after the request for transplantation at the time of the patient's death. This created two groups with different levels of stress and cognitive load during the request.

Two versions of the simulated request script were developed for the intervention groups by listening to audio recordings of actual telephoned GTEx requests from two participating OPOs. Because the first intervention group was intended to manipulate only the environment in which the request was heard, requests to members of this intervention group mimicked the OPOs' procedures for tissue requests by offering a short, general introduction to the project, followed by a verbatim reading of the authorization form (this is the direct intervention group). The requests made to the second intervention group mirrored the content of the presentation made to the first intervention group, but also manipulated the *delivery* of the request by including more lay language and incorporating several pauses and question prompts to check FDMs' understanding of the information provided to them (this is the enhanced intervention group). Once the presentations were developed, all five OPO partners reviewed and approved the simulated request scripts for fidelity to the OPOs' practices and the inclusion of all required elements for authorization. A single research assistant, trained to complete both types of requests, performed all of the simulated requests. All of the relevant institutional review boards approved this study, and verbal informed consent was obtained from all of the participants.

Study Samples. FDMs in the intervention groups were randomly selected and recruited from those agreeing to participate in a separate large national study examining the authorization process for organ donation (N = 1,503). In all, 373 of these FDMs were invited to participate in the intervention

groups, and 150 (40.2 percent) accepted the invitation and were randomly assigned to receive a presentation in either the direct intervention group (n = 74) or the enhanced intervention group (n = 76).

To generate a comparison group, each participant in the intervention groups (n = 150) was matched with an FDM enrolled in the ELSI substudy (n = 325) based on gender, race, age, income, education, religion, and marital status. Initially we aimed for perfect matching on gender and race and close matching on the remaining variables. This aim was achieved with a rate of 98 percent and 100 percent for gender and race variables, respectively. Male/female ratios were 40/110 and 43/107 for the comparison group and intervention groups, respectively.

Participants in both the comparison group and the intervention groups were recruited with invitational packets mailed to eligible FDMs (two months after a patient's death, in the case of the comparison group) using a protocol developed for analogous past research.[15]

Measurement

As part of their participation in the ELSI substudy, FDMs in the comparison group completed an hour-long, semistructured telephone interview two to three months after authorizing organ and tissue donation for transplantation and being approached for GTEx. The interview was developed and validated from our previous work with this population, and has been described in detail elsewhere.[16]

Upon enrollment in the current study, FDMs in the intervention groups were first prompted to recall their experience of being asked to donate their family member's organs and tissues. They were then asked to imagine a subsequent simulated request for GTEx immediately following that experience. After experiencing the simulated request, FDMs in both of the intervention groups were prompted for a decision about GTEx donation (agree/refuse). Two months after the simulated request, FDMs in the intervention groups were recontacted to complete a modified version of the interview used with the comparison group; the interview was shortened as appropriate to fit the unique experiences of these FDMs. Below we describe the variables relevant to the current investigation and their measurement.

Recall. Several questions assessed the participants' recall of the information provided about GTEx and biobanking. First, participants were prompted to recall two key terms (yes/no): (1) GTEx—the name of the study and (2) biobank—a term that was used frequently during the GTEx request. Participants were then provided a brief explanation of the project: "A biobank is a place where donated tissue samples are stored so that researchers can use them to study diseases. This biobank provides tissues to researchers to study how people's genes might play a role in their developing certain diseases. GTEx is the name of this biobank." The comparison group received additional information: "After you were asked to donate tissues for transplantation, the person who discussed transplantation with you also asked you to donate [patient's name]'s tissues to a biobank."

All of the participants were then asked whether they remembered the request to donate the patient's tissues to that research project (yes/no). A separate variable was created to indicate whether participants recalled the request before or after the explanation (0 = before/1 = after).

Knowledge/Comprehension. There were 17 questions asked that gauged respondents' understanding of the specific tissues that had been requested, the use of the tissues, participants' confidentiality, the potential linkage of the patient's tissues to medical records, the return of results, access to the samples, and the ability to withdraw the samples from the study (1 = true/0 = false). An index was created representing the number of questions a participant answered correctly. The questions are provided in the appendix at the end of this article.

Experimental Condition. The main independent variable was the condition under which the request was made to the participants. Three groups were generated. (1) The comparison group was comprised of FDMs who were asked to donate to GTEx immediately following a request to donate organs for transplantation. (2) The direct intervention group was comprised of FDMs who made a decision to donate organs for transplantation at the time of a loved one's death. Three to four years after the original donation request they were exposed to a simulated GTEx request using the same verbatim reading that members of the comparison group received. (3) The members of the enhanced intervention group were identical to that of the direct intervention group, except that the delivery of the GTEx request information used a conversational technique.

Statistical Analysis. Descriptive statistics were used to summarize participants' characteristics. Multivariate logistic regression was used to compare two groups at a time on three outcome variables simultaneously: (1) recall—before or after; (2) recall—GTEx; and (3) recall—biobank. Using a path-analytic specification of the model, all available data were used to estimate the model's parameters simultaneously, using the full information maximum like-

lihood method. Odds ratios (ORs) and their respective 95 percent confidence intervals (CIs) were used to present the results. Poisson regression was used to test group differences in the number of knowledge/comprehension items answered correctly.

RESULTS

Participants' characteristics are presented in table 1. Members of the comparison group and of the intervention groups were predominantly female, middle-aged, and White, with some college education. The matched samples had similar racial/ethnic make up, with 82 percent of each group identifying as White. To assess the success of matching, we reviewed seven matching variables and the patient's cause of death and found no significant differences between the groups (all p values > 0.10). Similarly, no significant differences were found between the two intervention groups (direct indirection versus enhanced intervention) on this set of variables (all p values > 0.10), indicating that the matching was successful.

The results of multivariate logistic regression are presented in table 2. Relative to the matched comparison group, members of the direct intervention

TABLE 1. FDMs' sociodemographics by group

	Intervention group					
Demographic characteristic	Comparison (n = 150)		Direct (n = 74)		Enhanced (n = 76)	
Income	$50 to $59K		$50 to $59K		$60 to $69K	
	Mean years	SD	Mean years	SD	Mean years	SD
Age	52.2	13.6	54.2	13.9	54.5	13.9
Education	14.4	2.3	14.7	2.3	14.4	2.1
	n	%	*n*	%	*n*	%
Sex—female	110	73.3	51	68.9	56	73.7
Race						
Black	17	11.3	5	6.8	10	13.2
White	123	82.0	63	85.1	60	78.9
Other	9	5.3	5	6.9	4	5.2
Marital Status						
Never married	19	12.7	6	8.1	9	11.8
Married/cohabit	48	32.0	32	43.2	24	31.6
Divorced/separated	9	6.0	7	9.5	7	9.2
Widowed	69	46.0	27	36.5	36	47.4
Religion						
Roman Catholic	34	22.7	20	27.0	20	26.3
Other	26	17.3	17	23.0	11	14.4
None	20	13.4	11	14.9	10	13.2
Relationship to patient						
Spouse	70	46.7	27	36.5	34	44.7
Parent	27	18.0	22	29.7	16	21.1
Sibling	22	14.7	6	8.1	12	15.8
Offspring	27	18.0	14	18.9	12	15.8
Other	1	0.7	4	5.4	2	2.6
Willing to donate own tissues—yes	140	93.3	65	87.8	72	94.7

Note: Percentages may not sum to 100 due to missing values. SD = standard deviation.

group were 38 percent more likely to recall the GTEx project before or after the explanation ($p < .001$), and 33 percent were more likely to recall the term biobank ($p < .01$). Similarly, members of the enhanced intervention group were nearly twice as likely to recall the term biobank ($p < .01$) than those in the comparison group. Members of the enhanced intervention group demonstrated considerably better recall of the term biobank than members of the comparison group (93 percent more likely; OR = 1.93). The direct intervention group also outperformed the matched members of the comparison group (33 percent more likely; OR = 1.33). While members of the enhanced intervention group who received an open reading of the script were more likely to recall the GTEx project before or after the explanation than were the matched members of the comparison group, the difference was not significant ($p > .10$). There were no statistically significant differences between the two intervention groups on their recall of the request or of the terms biobank or GTEx. Regarding the knowledge items, results from the Poisson regression indicated participants from neither intervention group exhibited significantly more knowledge than the respective matched members of the comparison group (all p values > .10).

DISCUSSION

Our data suggest that the limited recall and knowledge observed in FDMs who received the original, standard request for GTEx donation might have been due to the heightened emotions and/or physical fatigue that they experienced at the time of the request. The FDMs in both intervention groups had better recall of the GTEx project. However, participants' knowledge about the specifics of the research project—such as an understanding of the types of tissues requested, the use of the tissues, confidentiality, the potential linkage of the patient's tissues to medical records, the return of results, access to the samples, and the ability to withdraw samples from the study—were the same across the groups. This lack of understanding is not only disappointing, it is concerning, given the level of detail provided about deceased donors to hundreds and potentially thousands of researchers worldwide. Our results indicate that the reduction of the level of cognitive load and the stressful environment in the intervention group was helpful for recall, but the change from a standard to a more conversational approach to deliver information showed no appreciable improvement in participants' knowledge. Moreover, differences between the intervention groups were negligible. These results indicate that removal of acute emotional stress resulted in increased recall, but, despite this, the complexity and perhaps novel nature of the topic made it difficult for individuals who had little exposure to the topic to understand the information being delivered.

Studies of living biobanking participants indicate that donors often struggle to remember elements of informed consent, but generally have a good understanding of the basic purpose of the research project.[17] This study of surrogate decision making for deceased patients indicates that deceased donation presents increased challenges, compared to living donation. Future researchers who seek tissue from deceased organ and tissue donor FDMs should consider how they might lighten the intrinsic cog-

TABLE 2. Group comparisons

		Intervention group		
Outcome	Statistic	Direct intervention group = 0 versus enhanced intervention intervention group = 1	Comparison group = 0 versus direct invervention group = 1	Comparison group = 0 versus enhanced intervention group = 1
Recall GTEx—before or after	%	65.8 versus 68.9	**39.5 versus 65.8**	62.2 versus 68.9
	OR (95% CI)	1.09 (.71 to 1.67)	**1.38 (1.15 to 1.65)**	1.20 (.79 to 1.84)
Recall—term GTEx	%	30.3 versus 20.3	18.7 versus 30.3	33.8 versus 20.3
	OR (95% CI)	.80 (.51 to 1.24)	1.20 (.97 to 1.49)	.73 (.47 to 1.13)
Recall—term biobank	%	48.7 versus 59.5	**26.3 versus 48.7**	**33.8 versus 59.5**
	OR (95% CI)	1.31 (.87 to 1.38)	**1.33 (1.11 to 1.61)**	**1.93 (1.27 to 2.94)**

Note: Significant group differences are given in **boldface.** OR = odds ratio. CI = confidence interval.

nitive load (that is, the complexity of the information) and the extraneous cognitive load (that is, the presentation of the information) carried by FDMs who are approached for authorization.

One way to reduce the intrinsic load placed on FDMs when they review an authorization form is to simplify the text by shortening the request script, reducing the level of reading comprehension, and improving the layout of information contained in all of the documents used.[18] Most FDMs received information in oral form; written or modern infographic approaches might improve their recall and knowledge. Experts agree that the most important information necessary to make decisions about donation for genomic research projects should be presented first, potentially as bulleted lists.[19] Research indicates that spending more time discussing consent increases understanding.[20] The more-conversational reading of the simulated request script used in the enhanced intervention group was designed to include question prompts and probes to help requesters assess FDMs' understanding of the information they received. This version of the script also allowed for pauses and reduced the rate at which information was presented.

Given the findings of this study, these conversational techniques showed some promise to improve recall, but more techniques may be needed to help grief-stricken FDMs sufficiently grasp information about genomic and biobanking research projects. Continuous communication with willing, participating FDMs may be the best way to fully inform grief-stricken FDMs about the details and implications of their decisions. We recommend leveraging the use of OPO partners, who already routinely communicate with donor families, to disseminate this information to FDMs. The GTEx project is currently exploring options to send messages of thanks and updates from researchers to donor families via partnering OPOs.

An intervention with living biobanking participants indicates that increasing interactivity during the request and informed consent processes by embedding multiple-choice questions for participants in the conversation and providing immediate feedback to staff improved participants' understanding in face-to-face and multimedia formats.[21] Further, we suggest training tissue requesters (TRs) to hold long-form, "off-script" conversations with FDMs about critical authorization elements prior to a verbatim reading of the authorization form. A national resource to train TRs to communicate effectively with grieving families about genomic research has been developed out of the findings from the GTEx project's ELSI study, and a pilot of such an intervention is currently being tested.

It is important to note that FDMs in the comparison group who were matched to FDMs in the direct intervention group exhibited the lowest levels of recall of GTEx. Given the success of the matching process and the lack of difference between the members of the direct intervention group and their matched members of the comparison group and the other groups, it is not clear why recall was lower for that subsample. More research is needed to understand the specific aspects of the authorization process that are best understood by participants and the concepts that FDMs find difficult to grasp.

Nonetheless, these findings have important implications for clinical practice. First, our findings could be applied to any surrogate decision-making situation wherein a surrogate is under an immense amount of stress and trauma, including decisions made in emergency rooms and intensive-care units about the treatment of patients and their participation in research.[22] These results are also directly applicable to the context of cadaveric donation. Clinicians regularly approach and request cadaveric donations[23] and anatomical dissection for medical education and research from grieving families.[24] These donations remain critically important to medical education and doctors' knowledge of anatomy;[25] however, there is a shortage of cadavers. Research indicates there is little public understanding of this type of donation, and programs often rely on unclaimed bodies.[26] Similar to requesting research donations from FDMs, there is no gold standard for making other cadaveric donation requests, and very few ethical guidelines.[27] Our findings and the model of authorization provided by the GTEx project provide some framework for approaching decedents' family members for cadaveric donation.[28] First, clinicians may find it helpful to approach discussions regarding requests for cadaveric and other posthumous donations mindful that the cognitive load borne by patients' next of kin may impede their understanding of this type of donation, especially of complicated details. That FDMs have full understanding of these requests is especially relevant, considering that cadaveric donation may entail potentially disturbing uses of a decedent's body, such as crash testing or body decay, and finding this out after donation may cause physiological harm to family members.[29] Second, the need to fully communicate the risks and benefits of genomic research with decedents, an area of little oversight or ethical guidance[30] to their living relatives, is also pertinent to cadaveric donation.

This study is the first to experimentally test the impact of the authorization environment and the delivery of information on biobanking participants' recall and understanding, but it does have limitations. We asked participants to access their long-term memories for recall of terms and concepts in the GTEx authorization process, which is an imperfect measure of FDMs' understanding at the time of authorization; greater differences between the comparison group and the intervention groups may have been observed if we had assessed recall immediately following the donation authorization process. Additionally, our study design makes it impossible to distinguish between recall bias, in which members of the subgroups present nonrandom differences, and simple recall error or memory lapses.[31] However, the study design, which incorporated a conversational, interactive intervention group, demonstrated a potential to reduce the likelihood of recall error, and underscores the importance of the emotional environment to FDMs' ability to recall. It also highlights how complex and unfamiliar this area is to the general public. This lack of familiarity diminishes the ability of individuals to understand information presented about biobanking. Finally, we did not measure FDMs' cognitive load during the donation authorization process, nor did we measure their familiarity with genomic research, GTEx, or biobanking prior to the donation authorization process. However, studies of laypersons' understanding of genomic research indicate major gaps in knowledge about these concepts.[32]

CONCLUSION

As we move forward into an era of large-scale, population-based genomic research that collects detailed, personal data consisting of complete genetic information, medical records, and psychosocial profiles, we need to revisit our standards that assure that participants in these studies understand what they are agreeing to. These issues loom large for studies such as GTEx, neurological studies of brain injuries, and PMI. Consent or authorization to these studies should move into the 21st century, and take advantage of technology that embraces notions of collaboration, engagement, and education of the public and FDMs as the research moves forward.

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APPENDIX

Knowledge Questions

By signing the consent form, I would have been agreeing to donate [patient's name]'s tissues to a biobank.

By signing the consent form, I would have been agreeing to include [patient's name]'s medical records in the biobank.

By signing the consent form, the researchers who would use the donated tissue would know [patient's name]'s exact identity.*

If I signed the consent form and the donated tissue were used for a research project, I would have been told what they learned about [patient's name]'s health.*

By signing the consent form there would have been a slight risk that [patient's name]'s identity could be found out.

By signing the consent form and donating [patient's name]'s tissues, there would have been a slight risk that the identity of my family could be found out.

When a person agrees to participate in the GTEx biobank it means that he or she would have consented to use of his or her tissues for:
- Medical research
- Genetic research
- Any studies, now or in the future
- Just one study*
- Indefinite storage of donated tissue
- Inclusion in a government biobank
- Research outside of the U.S.
- Research with for-profit companies

If someone were to donate tissues to the GTEx biobank, he or she would have the ability to:
- Remove the tissues from the storage facility whenever he or she wants to.
- Ask that information from the donated tissues be deleted from a project in which it is actively being used.*
- Ask that the donated tissues not be used in any future research studies.

Note: * indicates the correct answer is "false."

An International Legal Review of the Relationship between Brain Death and Organ Transplantation

Kiarash Aramesh, Hitoshi Arima, Dale Gardiner, and Seema K. Shah

ABSTRACT

The "dead-donor rule" states that, in any case of vital organ donation, the potential donor should be determined to be dead before transplantation occurs. In many countries around the world, neurological criteria can be used to legally determine death (also referred to as *brain death*). Nevertheless, there is considerable controversy in the bioethics literature over whether brain death is the equivalent of biological death. This international legal review demonstrates that there is considerable variability in how different jurisdictions have evolved to justify the legal status of brain death and its relationship to the dead-donor rule.

In this article, we chose to review approaches that are representative of many different jurisdictions—the United States takes an approach similar to that of many European countries; the United Kingdom's approach is followed by Canada, India, and influences many other Commonwealth countries; Islamic jurisprudence is applicable to several different national laws; the Israeli approach is similar to many Western countries, but incorporates noteworthy modifications; and Japan's relatively idiosyncratic approach has received some attention in the literature. Illuminating these different justifications may help develop respectful policies regarding organ donation within countries with diverse populations and allow for more informed debate about brain death and the dead-donor rule.

INTRODUCTION

The dead-donor rule is a well-established ethical and legal constraint on the donation of vital or-

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gans. It requires that, before the donation can proceed, a potential donor is determined to be dead. There remains, however, some controversy on whether the dead-donor rule is ethically necessary, as well as on the nature and definition of death.

For centuries there has been general consensus on the cardiopulmonary definition of death.[1] This consensus was challenged in the 1950s with the development of mechanical ventilation and advanced life-support technologies, because these technologies could create a differentiation between the loss of cardiac function and the loss of brain function in some patients.[2] In the 1960s, physicians and jurists struggled with whether brain death (typically defined as the irreversible loss of neurological function) was an acceptable way to determine death.[3]

In most Western countries, the law now recognizes brain death, and vital organs can be obtained from brain-dead patients for transplantation into patients in need, provided other legal requirements (such as appropriate consent) are met. Some scholars have claimed that there is an international consensus around the neurological criteria for death and the dead-donor rule. For instance, Wijdicks asserted in 2001 that "Physicians, health care workers, members of the clergy, and laypeople throughout the world have accepted fully that a person is dead when his or her brain is dead."[4] Bernat similarly maintains that "Over the last 40 years the determination of human death using neurological tests ('brain death') has become an accepted practice throughout the world but has remained controversial within academic circles."[5] Robertson categorizes the dead-donor rule as the "ethical linchpin of a voluntary organ transplantation system,"[6] while Magnus and colleagues contend that, "some critics of brain death seek to abandon the dead-donor rule. Whatever one thinks of the argument for that as a philosophical position, it is far out of touch with current accepted medical and legal standards and public opinion."[7]

These strong statements are belied by the fact that there is limited information in the literature about the different ways international legal jurisdictions justify brain death and its relationship to the dead-donor rule. Scholars have conducted analyses of the views of various religious traditions regarding brain death,[8] the approaches to obtaining consent for organ donation in different jurisdictions,[9] and different medical criteria for diagnosing brain death,[10] but, to our knowledge, this article is the first to focus on the different ways that international jurisdictions have come to justify organ transplantation from brain-dead patients.

In this article, we report on an international legal review of various jurisdictions (the U.S.; the U.K.; countries subject to Islamic jurisprudence, such as Iran, Saudi Arabia, and Indonesia; Japan; and Israel). We chose to review approaches that are representative of many different jurisdictions—the U.S. takes an approach similar to many European countries; the U.K.'s approach is followed by Canada, India, and influences many other Commonwealth countries; Islamic jurisprudence is applicable to several different nations; Israel's approach is similar to mainstream Western countries, but includes noteworthy modifications; and Japan's relatively idiosyncratic approach that has received some attention in the literature. We found there is greater variability in the legal justifications for brain death and its relationship to the dead-donor rule than scholars have recognized. In Islamic traditions in particular, the notion of *unstable life* is a way to justify organ donation from brain-dead patients that we believe has not been fully described previously in the literature. Illuminating these different justifications may help the development of respectful policies regarding organ donation within countries with diverse populations and allow for more informed debate about brain death and the dead-donor rule.

THE UNITED STATES

In the U.S., the major source of organs is donors who have been determined to be dead by neurological criteria.[11] The law governing the determination of death in the U.S. is well known, and will be only briefly discussed. For much of U.S. history, death was defined using cardiopulmonary criteria, or, in lay terms, when the heart stopped beating and breath ceased. *Black's Law Dictionary* historically defined natural death as "The cessation of life; the ceasing to exist; defined by physicians as a total stoppage of the circulation of the blood, and a cessation of the animal and vital functions consequent thereon, such as respiration, pulsation, etc."[12] As noted above, in the 1950s and 1960s, for the first time, technologies enabled patients to persist in an irreversible coma after sustaining significant brain damage. In 1968, Henry Beecher's Ad Hoc Committee of the Harvard Medical School responded to these changes by proposing an additional way to determine death based on the permanent cessation of neurological functioning.[13] This article had a profound worldwide influence on the legal acceptance of brain death as death.

Nevertheless, acceptance of the concept of brain death in the U.S. was slow.[14] In the 1970s, some states passed laws recognizing neurological criteria for

death, but with considerable variability in the language used in their statutes.[15] In its 1981 report, entitled *Defining Death: Medical, Legal, and Ethical Issues in the Determination of Death*, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research sought to achieve national consensus about brain death. The commission rejected the "higher brain" definition for brain death and endorsed the "whole brain" definition.[16] This report also included proposed statutory language to move towards a uniform approach for all states. It further led to the creation of a draft law by the National Conference of Commissioners on Uniform State Laws, namely the Uniform Determination of Death Act (UDDA), which has now been adopted by all U.S. states and the District of Columbia in some form.[17]

Thirty-six U.S. states, the District of Columbia, and the U.S. Virgin Islands adopted the UDDA directly, and the rest of the states adopted very similar legal standards through legislation or court cases.[18] The UDDA holds as follows: "An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead."[19] The dead-donor rule is a separate legal constraint in the U.S. that is governed by state law and ensures that organ donation occurs only after death is determined. As Robertson explains, "if the organ donor is not dead, removing vital organs would cause death and potentially be punishable as homicide" under state law.[20] Thus, under U.S. state laws, organ donation from brain-dead donors does not violate the dead-donor rule because whole brain death is a form of death that is legally recognized throughout the U.S.

In light of recent controversy in the U.S. over the treatment of brain-dead patients,[21] it is worth noting that at least four states (California, New York, Illinois, and New Jersey), allow for reasonable accommodation of patients and families who do not believe in neurological criteria for death.[22] New Jersey requires the most of physicians and hospitals with respect to accommodation:

> The death of an individual shall not be declared upon the basis of neurological criteria . . . when the licensed physician authorized to declare death, has reason to believe, on the basis of information in the individual's available medical records, or information provided by a member of the individual's family or any other person knowledgeable about the individual's personal religious beliefs that such a declaration would violate the personal religious beliefs of the individual. In these cases, death shall be declared, and the time of death fixed, solely upon the basis of cardiorespiratory criteria.[23]

In states that require reasonable accommodation of patients and families who do not believe in the concept of brain death, however, questions remain about the limits on what physicians, hospitals, and insurance companies must do for brain-dead patients.[24]

THE UNITED KINGDOM

There is no law or statute defining death in the U.K. Although the Human Tissue Act (2004),[25] which regulates transplantation in England, Wales, and Northern Ireland, empowers the Human Tissue Authority (HTA) to define death for the purposes of the act, the various HTA *Codes of Practice* and the Human Tissue (Scotland) Act 2006[26] and Human Transplantation (Wales) Bill 2013[27] are silent on the issue. However, following a number of legal cases deciding this issue, brainstem death is accepted in common law as a definition of death.

Brainstem death was first addressed by the English courts in *R v. Malcherek; R v. Steel* in 1981. The court of appeal heard two separate appeals, in which each defendant claimed the actions of doctors had broken the chain of causation.[28] In each case, doctors had discontinued mechanical ventilation once their patient had been determined to meet the criteria for brain death.[29] In his judgment, Lord Lane observed, "There is, it seems, a body of opinion in the medical profession that there is only one true test of death and that is the irreversible death of the brain stem, which controls the basic functions of the body such as breathing." He concluded that these doctors did not break the chain of causation without providing a legal definition of death:

> This is not the occasion for any decision as to what constitutes death. Modern techniques have undoubtedly resulted in the blurring of many of the conventional and traditional concepts of death. . . . It is no part of the task of this court to inquire whether the criteria, the Royal Medical College confirmatory tests, are a satisfactory code of practice. It is no part of the task of this court to decide whether the doctors were, in either of these two cases, justified in omitting one or more of the so called 'confirmatory tests.' The doctors are not on trial.[30]

In 1992, proceedings were brought in *Re: A* to clarify the legality of the proposed disconnection of mechanical ventilation in a child.[31] Judge Johnson ac-

cepted the definition of death as recommended by the Medical Royal Colleges and their Faculties, namely brainstem death, and ruled that A was now dead for "all legal, as well as medical, purposes."[32] Two features of this ruling are worthy of note. Firstly, to declare that a patient is dead, Judge Johnson ruled that doctors must satisfy the various recommendations of the Royal Colleges as to the procedure to be adopted in the diagnosis of brainstem death. This has been interpreted as giving legal weight to the Royal Colleges' *Code of Practice* and, presumably, its successors.[33] Secondly, Judge Johnson ruled that "A" had been dead since the time of completion of the first set of brainstem death tests. This has led to the odd situation in the U.K. that although brainstem death is not confirmed until after the completion of the second set of brainstem death tests, the time of death is retroactively backdated to the time of the completion of the first set of tests. The significance of this feature has increased over time, as every successive *Code of Practice* has strengthened the recommendation that two sets of tests are undertaken. While in 1976 it was "customary" to repeat the tests, in 1983 the Department of Health recommended, "if the tests confirm brain death they *should nevertheless* be repeated."[34] By 1998 the Academy of Medical Royal Colleges' *Code of Practice* specified that "two sets of tests *should always* be performed,"[35] and the most recent version of the *Code of Practice* in 2008 states that testing "*must always* be performed on two occasions."[36]

The case law that followed has continued to accept brainstem death as death.[37] In *Bland*, the House of Lords explicitly endorsed brainstem death criteria when considering the case of Anthony Bland, who was in a persistent vegetative state:

> I start with the simple fact that, in law, Anthony is still alive. It is true that his condition is such that it can be described as a living death; but he is nevertheless still alive. This is because, as a result of developments in modern medical technology, doctors no longer associate death exclusively with breathing and heart beat, and it has come to be accepted that death occurs when the brain, and in particular the brain stem, has been destroyed.[38]

Brainstem death was last addressed in 2015, when the Honorable Mr. Justice Hayden quoted extensively from the 2008 *Code of Practice* and again upheld that irreversible cessation of brainstem function was sufficient to establish the criteria for death.

In all the cases taken to the English courts, organ donation and transplantation were not features of the cases under discussion. There is thus an acceptance in the U.K. that brainstem death is death, irrespective of any consideration of organ donation. Recommendation 7 of the 2008 Organ Donation Taskforce report, endorsed by all four U.K. health departments, was that brainstem death testing should be carried out in all patients in whom brainstem death is a likely diagnosis, even if organ donation is an unlikely outcome.[39] This recommendation was reinforced in the 2008 *Code of Practice* by the removal of all reference to organ donation.[40] The code is intended to apply to the diagnosis of death in all circumstances irrespective of organ donation. Additionally, the 2008 code included for the first time criteria for diagnosing death after cardiorespiratory arrest, again irrespective of organ donation.[41]

The U.K. legal standard is distinctive in that it accepts brainstem death as opposed to the more internationally common "whole" brain death. This has been a feature of U.K. practice since the original 1976 Royal Colleges' recommendation, which stated, "permanent functional death of the brainstem constitutes brain death."[42] This position has been restated in every succeeding Code of Practice. The 2008 *Code of Practice* states:

> Death entails the irreversible loss of those essential characteristics which are necessary to the existence of a living human person and, thus, the definition of death should be regarded as the irreversible loss of the capacity for consciousness, combined with irreversible loss of the capacity to breathe. . . . The irreversible cessation of brain-stem function whether induced by intra-cranial events or the result of extra-cranial phenomena, such as hypoxia, will produce this clinical state and therefore irreversible cessation of the integrative function of the brain-stem equates with the death of the individual.[43]

It is important not to overstate the importance of the U.K. criteria's reliance on death of the brainstem.[44] The capacity to breathe is considered to be a brainstem function (not a spinal or lung function), with specific exclusion in the *Code of Practice* for relying on clinical examination when the possibility of quadriplegia or profound neuromuscular weakness exists.[45] Likewise, the capacity for consciousness incorporates the capacity for arousal, another brainstem function, which is present even in patients in vegetative states, excluding them from being considered to fall under the U.K. criteria for death.[46] The pre-eminence, from the very beginning, of the brainstem in the U.K. criteria may have been influenced by the eminent pathologist, Keith Simpson.

In 1964, he was asked how one can know someone is dead and stated, "there is life so long as circulation of oxygenated blood is maintained to live brainstem centres."[47]

All international brain-death criteria require the loss of brainstem function. The U.K. criteria could be interpreted then as a basic global minimum standard; however, the U.K. criteria have always been an explicit rejection of whole-brain criteria, when that is defined as loss of all functions of the brain. The U.K. criteria affirm the scientific evidence to date that consciousness and breathing are not possible without a functioning brainstem. While there is this difference between the U.K. and most other countries (Canada and India also accept brainstem criteria), the overwhelming majority of patients who are confirmed to be brain dead in the U.K. would also be confirmed as brain dead elsewhere, and the diagnosis of death in isolated brainstem injured patients is a very rare event in the U.K., estimated to be a once in a decade experience at large neuro-intensive care units.[48]

ISLAMIC LAW

There are two main branches of Islam—Shiite and Sunni—each with its own jurisprudential, theological, and ethical schools. Traditional Islamic societies regulate brain death and organ transplantation with Islamic jurisprudence (*fiqh*).[49] Islamic jurisprudence, including both Shiite and Sunni schools of jurisprudence, has four main sources. The first and most important one is the Holy Qur'an, which is the primary source of Islamic jurisprudence and ethics. The second source is *Sunna*, which is what the prophet (and 12 *Imam*s who followed him, according to the Shiite school) said, did, or agreed to. The third source is *ijma*, which is the consensus of Islamic scholars, and the fourth is reason (*aghl*) in the Shiite schools, and analogical deduction (*qiyas*) in the Sunni schools of jurisprudence.[50]

According to Islamic teachings, death occurs upon the separation of the soul (*nafs*) from the body. This separation is not the subject of direct empirical observation. Although it is the focus and the main theme of many of verses in Quran, no biological criteria for death are provided.[51] In the Holy Scripture and in the books written by Muslim jurists in the medieval period, which still comprise the main references of Islamic jurisprudence (*fiqh*), almost no attention has been paid to the exact definition and physical criteria of death. Instead, it was submitted to the convention of ordinary people and physicians.[52]

The philosophical/theological relationship between the human brain/mind and the soul, and the role of the brain in intellectual functions like memory or cognition or moral judgment (which are traditionally attributed to the soul), are unclear in both Shiite and Sunni Islamic theologies.[53] Accordingly, Muslim jurists usually hesitate to consider a brain-dead person as having no intellectual capacity. This doubt is based on the theoretical possibility that if the human body and human spirit/soul (*ruh/nafs*) are still somehow connected in a brain-dead person, then the person can still have an intellectual life (which would allow, for example, an opportunity for redemption), even if this is not detectable by physicians or cannot be reversed to a detectable state. Other theories, such as defining life as embodied consciousness, have been proposed by some Muslim scholars to justify equating brain death with legal death,[54] but they have not found broad acceptance among Muslim physicians and jurists.[55]

Neither Sunni nor Shiite Islam has a single religious body that issues religious opinions and decrees. Rather, there are multiple councils and authorities, such as muftis among Sunnis, and Grand Ayatollahs among Shiites, who issue such religious decrees (*fatwa*s).

The Sunni Perspective

The majority of Muslims in the world are Sunni (about 90 percent). Sunni jurisprudence (Islamic law or *Sharia*) has a profound influence on the lifestyle and decision making of Muslims, and also is considered an influential source of law in many countries, including Saudi Arabia, the Arab Gulf States, Nigeria, Bangladesh, Indonesia, and many countries in the Middle East.

Sunni jurisprudence relies mostly on the Holy Scripture (Holy Quran and *Sunna*). Because no exact definition of death is specified in the Scripture, determining death is left to the convention of experts, who, in this case, consist of physicians. In addition, the principle of public good (*maslaha*) and the quotations from the prophet (*hadiths*) that urge Muslims to seek treatment and preserve their health and life led the majority of Islamic scholars to accept organ donation from brain-dead patients. This conclusion is justified either by equating brain death with cardiovascular death, or by considering brain death as an intermediate stage between life and death, which will be explained in greater detail below in the section discussing the Shiite perspective.

Among the views of Sunni Muslim juridical councils and expert groups regarding the concept of brain death, five are most prominent.[56]

1. In 1986, the Third International Conference of Islamic Jurists in Amman/Jordan passed a resolution with a majority of votes that equated brain death with legal death. The importance of this resolution is clear, as it paved the way for establishing programs of organ donation from brain-dead persons in some conservative Sunni countries, such as Saudi Arabia.[57]

2. In 1988, the Organization of Islamic Conferences' Islamic Fiqh Academy (OIC-IFA) took the position that Islamic law has two legal standards for the declaration of death: (a) when all vital functions of the brain end irreversibly and the brain has started to degenerate, as determined by expert physicians; (b) when heartbeat and respiration cease fully and irretrievably, as declared by physicians. This verdict explicitly considered the two legal standards to be equal. The OIC-IFA does not specify whether the whole-brain or brainstem criteria of brain death would fulfill these conditions.[58] This dual definition of death has been the subject of criticism by other Muslim scholars, who claim that it causes ambiguity and is not consistent with the teachings of the Quran.[59]

3. Similarly, the Islamic Medical Association of North America (IMANA) issued a briefing after consultations with Islamic scholars and reviews of juridical opinions. According to the IMANA's perspective, a person is considered dead when the functions of the brain, including the brainstem, have permanently ceased, even if some other organs may continue to show vital activity.[60]

4. U.K.'s Muslim Law Council, after a long course of discussions involving both Sunni and Shiite scholars in 1995, took the position that medical doctors are the proper authority to determine the criteria of death. In reliance on medical opinion in the U.K., brainstem criteria are accepted for determining death.[61]

5. In 1985, the Islamic Organization of Medical Sciences (IOMS), which consists of Islamic scholars and medical scientists, equated brainstem death with *al hayat ghair al mustaqirr* (unstable life) within Islamic law, and allowed for removal of life support, but not formal declaration of death for a person in such a state.[62] This position is similar to the one adopted by Shiite scholars and will be discussed in greater detail below.

The Shiite Perspective (Iran)

Whereas the majority of Muslims in the world are Sunni, the vast majority of Iranians are Shiite. Iran is the only country in the world in which, according to its constitution, laws and regulations must be based on Shiite jurisprudence (*fiqh*). As mentioned above, diagnostic criteria for death are not established by classical references of Islamic (including Shiite) jurisprudence. Instead, this subject is discussed in detail in the part of Islamic texts that address hunting and the legality of consuming a hunted or decapitated animal. It is important for Muslims to decapitate a hunted animal before it dies, because an animal is allowed to be consumed only if it was ritually decapitated while it was alive. Therefore, scholars have debated how one can understand whether a hunted and injured animal is still alive (such that it can be decapitated and consumed) or is already dead (such that its consumption is forbidden). In attempting to answer this question, Muslim jurists defined two states of life: the stable state of life (*al hayat al mustaqirr*) and the unstable state of life (*al hayat ghair al mustaqirr*).[63] The stable state of life is the conscious and normal state of life. The unstable state of life, however, describes the life of a hunted animal that is near death, with imminent cessation of cardiac and respiratory activity.

Shiite jurists in Iran have used this theoretical background to explain how organ procurement could be permissible from brain-dead donors.[64] Subsequently, the Organ Transplantation and Brain Death Act, once rejected in 1995, was approved by Iran's parliament in 2000, permitting organ transplantation using brain-dead donors.[65] According to this act, the organs of brain-dead persons, with the consent of their close relatives, can be transplanted to persons in need, provided that doing so is necessary for saving a life. Accordingly, only the transplantation of vital organs like the heart can be considered a legitimate reason to end a brain-dead person's life. Using other organs that would not save the life of another, like a kidney or cornea, would only be permitted after first removing the donor's heart, which is understood to result in the death of the donor (who was previously understood to be alive in an unstable sense).[66]

According to Islamic teachings, human life is sacred and should be protected and preserved. It is forbidden and considered a sin to take an innocent human life. By using the concept of unstable life, the Muslim jurists refrain from accepting brain death as equal to death, and, at the same time, pave the way for lifesaving organ transplants from brain-dead persons. In sum, under Shiite jurisprudence, brain-dead persons are still alive and their life is sacred, so it is forbidden to remove life support and declare them dead, but it is permitted to sacrifice their sacred but "unstable" life in order to save a stable,

more valuable life. Therefore, one can argue that Islamic/Shiite jurisprudence takes a somewhat utilitarian approach in this type of case.

ISRAEL

According to the Israeli law, the Chief Rabbinate Council of Israel is the supreme rabbinic and spiritual authority in Israel. The Chief Rabbinate Council is made up of two chief rabbis who serve a 10-year term and are selected by representatives of both secular and religious communities. The council is in charge of providing responses and opinions on matters of religious law to persons seeking its advice.[67]

The need to provide organs for transplantation led the Chief Rabbinate Council of Israel to issue a religious decree in 1986 that accepted brain death as a valid determination of death.[68] Nevertheless, a consensus does not exist among different branches of Judaism regarding the concept of brain death.[69] For example, ultra-orthodox Jews follow a strict interpretation of the *halacha* (the collective body of Jewish religious laws derived from the Written and Oral Torah) and define the time of death as the moment of cessation of respiratory function; therefore, they do not accept brain death as biological death, as long as breathing continues (even if it requires mechanical support through a ventilator). In addition, the principle of the sanctity of life makes Jewish religious authorities hesitant to accept radical changes in the criteria of death.[70]

In an empirical study, a large portion of the Jewish population who consider themselves to be "religious" or "religious-traditionalist" said that they rejected organ donation after brain death because they did not consider brain death as a type of death.[71] However, a group of Jewish scholars argues that brain death is similar to decapitation, and since, according to the *halacha*, a decapitated animal is considered dead—despite the persistence of some vital functions in its body—the brain-dead person should also be considered dead.[72]

A clinical guideline promulgated by the Israeli Ministry of Heath regulated the determination of brain death in Israel from 1996 to 2008. This guideline was based on the practice parameters of the American Academy of Neurology. In 2008, the Knesset (the legislative branch of the Israeli government) passed the Brain-Respiratory Death Act into law; this included most of the requirements of religious authorities, the most important one being that death may only be determined when *spontaneous* respiratory functions terminate permanently.[73] Although "permanent loss of spontaneous respiratory functions" is also required by any jurisdiction that accepts brain-death as biological death, Israeli law emphasizes that brain death explicitly accommodates and incorporates the Chief Rabbinate Council's requirement for cessation of spontaneous respiration.

In the years following its implementation, the Brain-Respiratory Death Act has been modified and amended. For example, in the first version of the act, a patient's family members were informed of the intention to perform brain-death testing before performing the tests; however, according to the new version of the act, physicians are to seek information on the patient's views on brain death in writing. The rationale behind this change is to take into consideration the strong religious views of ultra-orthodox Jews that brain death is not equivalent to death. In addition, in the new version of the act, the apnea test and ancillary testing are mandatory; physicians have to undergo training that includes medical, ethical, and religious components before they can make brain-death determinations, and an authorization committee oversees determinations of brain death in hospitals to ensure that they are performed in accordance with the requirements of the Chief Rabbinate Council. It has been argued that these changes were made to accommodate the orthodox minority of the population and that they impose hurdles that lower the number of cases of determination of brain death and organ donation.[74]

In conclusion, although Israel formally validated the concept of brain death through the Brain-Respiratory Death Act, the law contains unique protections designed to ensure that vital organs are not removed from those with religious objections, protections that arguably have reduced vital organ transplantation in the country overall.

JAPAN

Japan's Organ Transplantation Law was first enacted in 1997 and was revised in 2009. One of the major changes in the revised law concerned the rules of consent for organ donors, which is important to understanding the controversy regarding the determination of death in Japan. The original law required donors to opt in and affirmatively choose to be donors, and gave veto power to the person's family. The revised law switched to an opt-out system, while its text still explicitly requires the consent of family members. The law also contains language that can be understood as providing a definition of death. Although interpretation of this language is some-

what controversial, insofar as the original law is concerned, it seemed obvious to many that individuals were allowed to define whether brain death would be death in their own case. Modifications to the definition of death were made during a 2009 revision of the law, and one plausible understanding is that the new law simply equates brain death with biological death. However, as we shall explain in this section, another understanding that is at least equally plausible is possible, according to which individuals are still entitled to choose whether or not to accept brain death as a legal form of death under the new law.

To understand the controversy, one needs to go back to the actual wording of the original law, and see how it could be interpreted as allowing individuals to define for themselves whether brain death is biological death. A sentence in Section 6 of the original law (which remained the same after the revision) maintains that "organs can be procured for transplantation from a dead body (including the body of a brain dead person. . . .)."[75] This indicates that brain death is equated with human death in Japanese legislation. But, in the original law, in an important qualifier, the sentence in the section that immediately follows states, " 'the body of a brain dead person' means the body of a person *whose organs are going to be procured for transplantation surgery* [*noushi shita mono no shintai toha sono shintai kara ishokujutsu ni shiyo sareru tame no zoki ga tekishutsu sareru koto to naru mono no de atte*] and whose whole brain, including its brain stem, is declared to have irreversibly ceased its functioning."[76] The important part of this, for our present discussion, is the first half of the qualifier, which should strike many as odd, due to the claim that whether a person is dead depends on what is going to occur afterwards, and, as we shall see, this part was eliminated in the 2009 revision.

In addition, as mentioned above, the law used to have a strong opt-in system to confirm a donor's wish to donate, maintaining that "organs may be procured for transplantation surgery" only if "the dead person had provided while alive a written will to donate organs for transplantation surgery."[77] The law also provided additional veto power to the family. So for organs to be procured, both the brain-dead person and the family needed to provide consent to donation.

Reading all these sentences together, a brain-dead person's body could be considered a dead body only when organs were going to be procured for transplantation, but organ procurement could occur only when the person gave prior written consent. In other words, based on this reading, a person is not dead even when the whole brain has irreversibly lost its function unless the person gave written consent to organ donation while still competent. Thus, for example, Makoto Ida maintained that "there is no other way but to understand that the law provides the 'choice of brain death' as an 'exceptional option.' "[78] This unorthodox manner of defining human death was also described with noted curiosity by Canadian anthropologist Margaret Lock: "Brain death is equated with death in Japan, therefore, *only* when patients and families wish to donate organs. The law refers to 'the body of a brain-dead entity' [*noshi shita mono no shintai*], but nowhere does it state explicitly that brain death is equivalent to human death."[79]

In 2009, the law was revised in a few significant ways. First, the opt-in system was replaced with an out-out system for confirming what the donor wanted.[80] Second, in the sentences defining human death, the phrase "whose organs are going to be procured for transplantation surgery and" was eliminated from the above sentence of Section 6. When the revised law first came out, media reports, including those in the major newspapers, stated that the new law equated brain death with biological death.[81] It appeared to be natural to think that that was what the revision intended to do, considering the content of the phrase that was eliminated. Nevertheless, a careful reading of the revised sentences suggests that the same problem, that is, that the definition of death is a matter of individual choice, remains.

The shorter Section 3 of the new law now reads, the " 'body of a brain dead person' means the body of a person whose whole brain, including its brain stem, is *declared* to have irreversibly ceased its functioning."[82] A further complication occurs due to the provision regarding the "declaration" of brain death. According to Section 6-3, doctors may make "The declaration concerning organ procurement mentioned in the preceding section" either when the brain-dead person, while competent, agreed to donation and the family does not object later, or when the brain-dead person did not express an opinion while competent, but the family later provided consent.[83] In other words, organs may be procured under the new law *unless* the patient had previously documented a refusal to donate organs. In Japan, as in most other countries, for a patient to be declared brain dead for purposes of transplantation, doctors must conduct a legally specified set of tests to make sure that the patient's conditions meet the criteria of brain death. Section 6-3 states that these tests

should be applied to a brain-dead patient only if the patient's willingness to donate organs is confirmed.

One implication is that there will be patients who have suffered neurological damage who refuse to donate organs, and therefore do not undergo testing to determine whether they meet the neurological criteria for brain death, and are not officially "declared" brain dead. Among these patients, there would be some who are in fact brain dead, according to the whole-brain formulation, but have not been declared as such. Reading the above two sentences of the new law together, therefore, it seems that the law now maintains that these patients (who are actually brain dead, but who are not determined to be so) are not dead. Or at least this is how the law is interpreted by some scholars today.[84]

The uniqueness of this Japanese legislation needs to be understood with care. Even in other countries, patients who are only apparently brain dead will not be treated as dead until their doctor conducts a legally specified set of tests to make sure that the patients' condition meets specific criteria. Further, many doctors will normally only conduct tests when a patient (or the family) agree to donate organs (or did not refuse to donate organs, in opt-out countries). Such decisions by doctors to test or not test will be guided as much by local practice and culture as by national guidance and law. Hence, the situation in many countries may, in practice, be substantially similar to Japan's.

Although the difference is subtle, the difference still remains. In those other countries where brain death is equated with biological death, this definition is understood to apply to everyone. In contrast, in Japan, as believed by some, the same definition of death does not apply to all. The new definition (equating brain death to human death) applies only to those who do not refuse to donate organs. If one refuses, the more traditional, cardiopulmonary definition applies.

Why this subtle (or rather trivial, one may think) difference in interpretation should be the subject of discussion in Japan is a question that is difficult to answer. However, a possible reason may be that it is often believed that Japanese people tend to resist the idea of equating brain death with biological death more than people in other cultures. One poll done by a major newspaper in 2009 reported that 40 percent of people agree that brain death is a form of biological death, but as many as 39 percent do not.[85] Thus it may be thought that allowing individuals to choose a definition of death for one's own case takes a pluralistic approach that is appropriate for Japan's situation.

To summarize, the definition of death in Japanese law is not very clear, and it leaves room for interpretation. A reasonable interpretation of the current law is that the definition of death is a matter of individual preference: individuals can choose whether to be considered dead even if they meet the neurological criteria for death, by way of expressing preferences regarding organ donation.

CONCLUSION

Although there is widespread legal support for vital organ transplantation from brain-dead donors, different jurisdictions take somewhat distinct approaches to justifying and determining brain death. It is noteworthy that some approaches are grounded in an understanding of when death occurs for other biological organisms, including other animals. Additionally, many jurisdictions attempt to respect the views of minority groups that brain death is not equivalent to death, but to different degrees and in different ways. Along with the continued controversy regarding brain death in the bioethics literature, this analysis indicates that much work remains to be done before there is a clear legal consensus on neurological criteria for death and the dead-donor rule. Moreover, approaches like the notion of "unstable life" in Islamic jurisprudence have not been well recognized, and offer a way to justify organ donation from brain-dead patients that does not rely upon the dead-donor rule. This review may help policy makers to develop appropriate guidance regarding organ donation within countries that have diverse populations, with different religious and cultural traditions, and may also spur more informed debate about the relationship between brain death and the dead-donor rule.

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Clinical Practice

The Bedside Capacity Assessment Tool: Further Development of a Clinical Tool to Assist with a Growing Aging Population with Increased Healthcare Complexities

Maria Torroella Carney, Brian Emmert, and Brian Keefe

ABSTRACT

Background

As the population of the United States ages, chronic diseases increase and treatment options become technologically more complicated. As such, patients' autonomy, or the right of patients to accept or refuse a medical treatment, may become a more pressing and complicated issue. This autonomy rests upon a patient's capacity to make a decision. As more older, cognitively and functionally impaired individuals enter healthcare systems, quality assessments of decision-making capacity must be made. These assessments should be done in a time-efficient manner at a patient's bedside by the patient's own physician. Thus, a clinically practical tool to assist in decision-making capacity assessments could help guide physicians in making more accurate judgments.

Objectives

To create a clinically relevant Bedside Capacity Assessment Tool (BCAT) to help physicians make timely and accurate clinical assessments of a patient's decision-making capacity for a specific decision.

Setting

The Department of Medicine, Division of Geriatrics and Palliative Medicine, Zucker School of Medicine at Hofstra/Northwell.

Participants

Geriatric medicine fellows, palliative medicine fellows, and internal medicine residents (n = 30).

Measurements

Subjects used the BCAT to assess the decision-making capacity of patients described in 10 written, clinically complex capacity assessment vignettes. Subjects' conclusions were compared to those of experts.

Results

The subjects' and experts' assessments of capacity had a 76.1 percent rate of agreement, with a range of 50 percent to 100 percent. With removal of three complex outlier vignettes, the agreement rate reached 83.2 percent.

Conclusion

The strong correlation between the two groups—one of physicians in training utilizing the BCAT and the other of specialists in this area—suggests that the BCAT may be a useful adjunct for clinicians who assess decision-making capacity in routine practice. The range indicates that further refinement and testing of this

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tool is necessary. The potential exists for this tool to improve capacity assessment skills for physicians in clinical practice.

INTRODUCTION

As the U.S. population ages, chronic diseases increase, and treatment options become technologically more complicated. As such, patients' autonomy, or the right of patients to accept or refuse a medical treatment, may become a more pressing and complicated issue. The doctrine of informed consent has its philosophical roots in the bioethical principle of autonomy and is the basis of the view that every competent patient has a right to make decisions about his or her medical care. Informed consent in healthcare requires that the patient be provided sufficient information to make a decision, be free from significant coercion in the decision-making process, and be competent to make decisions. In modern terms, *competency* is a broad concept, a product of the legal system, and declared by a judge. *Capacity* to make healthcare decisions, on the other hand, is the product of a clinical assessment—one that uses legally defined criteria, but is nevertheless offered by healthcare providers in a specific context and pertaining to a specific decision.

Primary care physicians and careproviders are increasingly consulting psychiatrists to assist with determining the presence or absence of the components of decision-making capacity.[1] All physicians are trained to and, therefore, should be able to describe and determine a patient's capacity to make decisions.[2] Therefore, it often is not advantageous for physicians, who may know a patient more thoroughly and perhaps over a longer period of time and understand the therapeutic options presented, to consult a new physician to evaluate a patient's decision-making capacity. This clinical assessment skill can be challenged by complex medical/surgical treatment options and individuals' level and ability to understand medical information.[3]

In practice, the components of decision-making capacity are often not well defined or articulated by clinicians. This is shown by the need to consult psychiatric specialists for decision-making assessments, which can contribute to delay in the delivery of care. As such, a variety of assessment tools have been developed to attempt to assist in capacity assessment.[4]

The assessment of decision-making capacity requires, at its core, comprehensive evaluation and description.[5] Four common criteria for decision-making capacity have emerged, as described by Appelbaum and Grisso in their seminal article from 1988.[6] These four criteria have helped to standardize the measurement of decision-making capacity.[7] First, the patient must be able to *communicate* a stable choice related to treatment or a diagnostic procedure. Next, the patient must demonstrate an *understanding* of the information provided by the clinician, repeating or paraphrasing the risks, benefits, and alternatives associated with the choice made. Third, the patient must show an *appreciation* for both the situation at hand and how it affects her or him personally. This is evidenced by the patient's grasp of the acuity or severity of the decision and its likely consequences. The fourth and final criterion involves an assessment of the *reasoning* employed by the patient to reach a decision. Regardless of the clinician's opinion of the advisability of the decision, the patient must demonstrate a rational manipulation of the information considered to reach the choice made.[8] For a satisfactory determination of decision-making capacity, all of the aforementioned criteria should be met.

Since all clinical interventions (diagnostic or therapeutic) require informed consent, the ability to quickly and accurately make a determination of a patient's decision-making capacity is essential in a busy clinical setting. This assessment is usually performed intuitively by physicians or is influenced by a careprovider's global assessment of cognitive functioning. However, these methods, especially when based on an assessment of global cognitive functioning, can be inaccurate.[9] A specific decision-making capacity tool would focus the clinician on specific criteria and introduce the possibility of enhancing the accuracy and rationale of these determinations. Using the four domains outlined by Appelbaum and Grisso, a series of assessment tools have been developed. These include, but are not limited to, the Competency to Consent to Treatment Instrument (CCTI),[10] the Structured Interview for Competency and Incompetency Assessment Testing and Ranking Inventory (SICIATRI),[11] and the MacArthur Competence Assessment Tool for Treatment (Mac CAT-T).[12] These instruments most commonly utilize structured interviews,[13] semistructured interviews,[14] and abstract readings with patients (reading vignettes of hypothetical medical cases and asking patients about their decision-making process).[15] The Mac CAT-T is considered reliable and effective, especially in psychiatrically complex patient populations and is a validated resource for clinicians' assessments. Unfortunately, neither the Mac CAT-T nor other tools are currently utilized by busy, bedside clinicians on a routine basis to guide or assist in capacity assessments.[16] There is a need to have a careprovider-friendly guidance tool

for a fast-moving clinical setting, as it takes 20 to 30 minutes to complete a structured, validated capacity assessment.[17] As a result of the increasingly complex patient population and medical therapies and interventions, the capacity of a patient may be unclear to many careproviders and family members. As such, with the increasing focus on patients' autonomy, there in an increased burden on physicians to make accurate capacity assessments. Development of a brief tool (that takes less than five minutes), that guides careproviders through the decision-making capacity assessment components and also fits into their already established clinical protocol of care, is needed.[18] This would reserve specialized consultations by psychiatrists or the use of the longer and more nuanced tools, such as the Mac CAT-T, as the ultimate resource for more challenging situations.

Furthermore, other instruments have been designed based on the concept that decision-making capacity occurs along a spectrum, which generate results that represent intermediate designations.[19] This concept does not provide clear guidance to clinical practitioners who must have a definitive capacity assessment to move forward with a treatment plan or revocation of decision-making capacity for the decision at hand. Thus, the development of a brief, user-friendly tool to assist clinicians in making a dichotomous (yes or no) determination of decision-making capacity for the decision at hand, as well as to clarify the issues behind the need to utilize surrogate decision makers, would be an important contribution to patient care.

The present study strives to further develop the Capacity Assessment Tool (CAT) developed by Carney and colleagues, with a goal of being more concise, careprovider-friendly, and educational. The CAT independently measured each of Appelbaum and Grisso's four criteria of decision-making capacity. When comparing a cohort that used this instrument with the assessment of expert psychiatrists, a strong correlation was observed.[20] The Bedside Capacity Assessment Tool (BCAT) development and piloting are described in the present article.

METHODS

Development of the BCAT

A focus group of geriatric medicine fellows who used the original tool was held to discuss the benefits and challenges of use of the CAT. The group made the following observations and recommendations regarding bedside capacity assessments:

- Decision-making capacity is a daily challenge faced by careproviders.
- The group reported that, previously, only "major issues" required formal comment, but now even "minor" issues are beginning to need a formal statement.
- A tool should be short and limited to one page.
- The instrument should limit each domain to a Yes/No/Unsure designation.
- The tool should be decision specific.
- The tool should be able to provide additional support for a clinician's assessment of capacity.
- The tool should address communication barriers between the careprovider and patient (for example, hearing aids, glasses, language, *et cetera*).

Consequently, we revised the CAT to create the Bedside Capacity Assessment Tool (BCAT)—a more concise and user-friendly assessment of decision-making capacity components.

The BCAT separately assesses each of Appelbaum and Grisso's four domains of decision-making capacity:

1. The ability to communicate a stable choice to make a specific decision. (Can the person communicate a choice, verbally or nonverbally, in a clear and understandable manner?)
2. The ability to understand relevant information about a treatment choice as well as the risks and benefits of the decision. (Is the patient's description of the relevant information about a treatment choice or medical/healthcare decision accurate? Does the patient understand the consequences of the decision on him- or herself?)
3. The ability to appreciate the situation and its consequences regarding the decision at hand. (Does the patient acknowledge the presence, nature, and severity of illness as it relates to him- or herself? Can he/she assess the effect of the illness and treatment options?)
4. The ability to manipulate information rationally and logically. (Has the patient been able to delineate sound reasoning and weigh the risks and benefits of a treatment that are consistent with the pre-existing personal, cultural, and/or religious values and beliefs held by the patient?)[21]

The BCAT must not replace the physician or careprovider's own clinical conversation regarding a treatment option and clinical evaluation of the patient. The BCAT tool should guide the clinician through the components of decision-making capacity, allowing the careprovider to determine if she or he has addressed each component sufficiently, as it pertains to the decision at hand. If the patient's ability is not clearly demonstrated in all four domains,

the careprovider, in practice, would have the ability to re-address and clarify further or explain more clearly why a surrogate decision maker would be needed for this clinical situation. Deeming a person to lack capacity to make that particular decision may need to be further evaluated. Thus, this tool should allow for both a decision-specific determination and a framework for further evaluation.

Once the tool was refined, we began to examine its efficacy through its use with complex clinical case vignettes as an initial step to pilot.

Subjects. This project to pilot test the BCAT was approved by the institutional review board (IRB). Thirty English-speaking subjects consisting of geriatric medicine fellows (different fellows than those in the tool development focus group), palliative medicine fellows, and internal medicine residents volunteered to participate in this study. Written informed consent was obtained from each subject. Subjects were debriefed and educated on the tool following completion of the task.

Vignettes. The research team developed 10 hypothetical clinical case vignettes that highlighted capacity determination dilemmas, based on referrals to inpatient psychiatry consult teams, thus representing more challenging cases. Each vignette consisted of a short medical history, background, and select observations of the patient, as well as an abridged transcript between the patient and the house officer (see appendix). Cases were written to invoke each of the four criteria of decision-making capacity and varied in degree of difficulty. Vignettes were written and edited by a team of six psychiatrists and geriatricians. Cases were written to meet a range of difficulty, from less challenging to highly complex.

Test Phase, Subjects used the BCAT to determine the decision-making capacities of the patients described in the 10 vignettes. The tool was developed to be self-explanatory, and therefore no instruction was given to subjects prior to the task; they were simply instructed to use the tool to make a capacity assessment. The subjects' capacity assessments were compared to answers provided by the expert authors of the case vignettes.

Analysis. The authors compared individual subjects' performance across all cases assessments to the experts' results. They also calculated the percentage of agreement on each case.

RESULTS

The mean rate of agreement between all of the subjects' and experts' assessments across the cases was 76.1 percent. The scores ranged from 50 percent to 100 percent agreement (sensitivity = 68.68 percent; confidence interval of 61.0-76.4 percent and specificity = 83.87 percent; confidence interval of 76.5 to 91.4 percent, standard deviation = 13.3 percent; see figure 1).

The authors calculated the agreement scores between subjects and experts for each case. The mean agreement rate for each case, across subjects, had a wide range. Case 7 had the lowest mean agreement, with a mean of 50 percent. Case 1 had the highest, with a mean of 100 percent (see figure 2).

In a *post hoc* analysis, we observed that three cases (cases 3, 7, and 10) had low concordance rates of 60 percent or less. We completed a secondary analysis without these three cases to examine the effectiveness of our tool in more clear-cut but challenging cases. With the removal of these cases, the mean agreement across the other seven cases was 83.2 percent (confidence interval of 72.9 to 93.4), with a range of 67 to 100 percent.

Of note, further analysis demonstrated that there was no mean difference in the rate of agreement

FIGURE 1. Agreement with research team assessments by trainee

across postgraduate year (F-ratio = .5151, $p = 0.7622$) (that is, postgraduate year one to postgraduate year four).

DISCUSSION

The determination of a patient's decision-making capacity is an important aspect of patient-centered care. In a fast-paced clinical setting, in which the clinical burden on careproviders is increasing, a primary careprovider needs a way to rapidly and accurately assess a patient's decision-making ability. The BCAT shows promise as a practical tool to address this unmet need. In this study, answers from relatively inexperienced physicians on a series of difficult clinical situations, that were expressed in hypothetical case vignettes, correlated well to expert-derived answers to the case vignettes. Thus, there is evidence that physicians are able to use this tool to assist in determining patients' decision-making capacity. Furthermore, as longitudinal careproviders, primary care physicians usually know individual patients better than independent consult teams do, as they often provide care on an episodic, problem-focused basis. Equipped with the knowledge of a patient's longitudinal preferences about care and quality of life, an appreciation for the patient's family's involvement, and an understanding of the patient's medical issues and treatment options, primary careproviders are often in the best position to ultimately judge a patient's decision-making capacity. In turn, primary careproviders may be better able to determine the need for surrogate decision making in the context of patient-centered care.

Our pilot study did observe vast variation in agreement between subjects and experts across three particular case vignette (case 3, case 7, and case 10), with agreement rates less than or equal to 60 percent. These cases were designed to be the most challenging and ambiguous. The rate of agreement for the remaining seven cases equaled 83.2 percent. It is possible that the vignettes with lower concordance rates were more ambiguous and challenging, not unlike real life, and would be better served by the use of a more detailed tool, such as the MacCAT-T, or a specialty evaluation by a psychiatrist. Another potential limitation in generalizing these data is that only one medical specialty was represented in the residents and fellows who participated in the study. As such, we cannot conclude that physicians of all specialties would have performed similarly using the tool. Since decision-making capacity assessment is typically done intuitively, we postulate that this tool, with fair agreement rates, will be effective for all specialties. It simply provides a format and structure for the assessment of capacity. However, future studies should utilize a wider spectrum of medical-surgical specialties, along with physicians with varying years of experience.

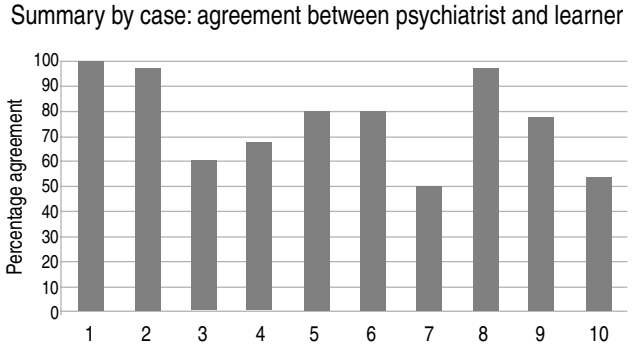

FIGURE 2. Learner assessment agreement with research team assessment, by case

Another potential limitation in the interpretation of the data is that the subjects were not given any instructions about how to use the BCAT before the test phase began. Rather, they just followed the instructions on the tool, leaving room for potential misinterpretation or misuse. In the future, it may be beneficial to provide education to subjects before they use the tool, thus removing any potential for varying application. However, our goal is to provide a self-sufficient and user-friendly clinical tool that requires little formal training, broadening the accessibility of formalized decision-making capacity assessments.

This study only provides information on how closely the subjects' results compared to the results of the team of experts. This study did not evaluate if the tool helped learners improve their accuracy against themselves or other physicians not using the tool. A study is currently underway to evaluate if the tool helps to improve assessment accuracy. Despite the absence of a study design that could demonstrate improved accuracy for BCAT users, we nevertheless postulate that the BCAT has potential as an educational instrument. When using the tool, clinicians are sequentially prompted to consider each of the four domains of decision-making capacity. Each category is clarified by a guiding question for the interview, intended to help elucidate the meaning of ability in that area. Thus, this tool can be used as a scaffold to teach students about the tenets of decision-making capacity.

The BCAT highlights the importance of an "all-or-none" determination of the ability to make a spe-

cific decision in the clinical setting. While informed consent scholars have sometimes viewed decision-making capacity as a continuum,[22] this view is clinically impractical. Intermediate values would not inform how to proceed in caring for a patient. Furthermore, each subcategory (communication, understanding, appreciation, and rationalization) that comprises the overall assessment also lies on a continuum. Thus, when patients falter in one of the subcategories, they may not have a full comprehension of the decision at hand, challenging their ability to make an informed decision. However, care-providers who ignore the fact that capacity lies on a continuum may too hastily challenge a patient's autonomy. Therefore, it is important to only award capacity for the clinical decision at hand and not to make a global determination. Capacity assessment in the healthcare context is decision specific, leaving open the possibility that patients can make other decisions. In the setting of fluctuating mental status, patients can be re-assessed at a different point in their illness, allowing for the possibility of restored capacity.[23] Practically speaking, if the clinical decision is not urgent, but nevertheless complex, more than one assessment may be needed before initiating the therapy or procedure or to seek support from surrogates to assist the patient in the decision-making process.

With an aging population and an increasing number of patients with multiple co-morbidities, an accurate and user-friendly bedside capacity assessment tool would be a useful addition to ensure the most rapid, appropriate, and informed treatment for the patient. The present study highlights the potential for the BCAT to fill this need, allowing physicians to more confidently make assessments of their patients' decision-making capacities and to help determine when further evaluation is needed, such as with use of the MacCAT-T or a psychiatric consultation. This study demonstrates an adequate correlation in decision-making capacity assessment between experts and physicians using the BCAT, but also demonstrates that further evaluation on some cases might be needed. A larger study utilizing a greater mix of physicians' subspecialties and experience level is needed to more confidently generalize the data from this study, as well as to determine its utility as an educational instrument.

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APPENDIX

Case Vignettes for the BCAT Study

Case 1: An 88-year-old widowed male is admitted to the medical service for a work up after he was found down on the floor at home by his neighbor. The patient has a history of type II diabetes mellitus, early congestive heart failure, and essential hypertension. The patient is able to articulate that he is "diabetic and high blood pressure" but cannot name the medications he is taking. A discharge summary from the year before notes "dementia" in the discharge diagnoses, but patient denies problems with his memory. On exam, he is gaunt, malnourished with bilateral edema of the lower extremities, and mild respiratory distress. He has bruises indicative of prior recent falls. He states he has no next of kin or any family to contact. The treatment team recommends nursing home placement. Upon bringing this information to the patient, and informing him, he states, "I don't really care." Asked if he could articulate why he thinks the treatment team may be recommending nursing home placement, he says only, "I don't know. I don't care. I won't discuss it." Further attempts at reviewing the option of discharge to a nursing home are met with persistent refusal to have such a discussion. Does this patient have the capacity to make a decision regarding nursing home disposition?

Part I: Components of decision-making capacity (check best answer):

1. The ability to communicate a stable choice to make a specific decision:

Can the person communicate a choice (verbally or nonverbally) in a clear and understandable manner?

☐ YES ☐ NO/NOT SURE

2. The ability to understand relevant information about a treatment choice:

Is the patient's description of the relevant information about a treatment choice or medical/healthcare decision accurate?

☐ YES ☐ NO/NOT SURE

3. The ability to appreciate the situation and its consequences regarding the decision at hand:

Is the patient generally aware of the medical condition and the nature of the severity of the medical condition and the likely consequences of his/her decision?

☐ YES ☐ NO/NOT SURE

4. The ability to manipulate information rationally:

Has the patient been able to delineate reasons for his/her decision that are consistent and in keeping with existing personal, cultural, and/or religious values and beliefs?

☐ YES ☐ NO/NOT SURE

Part II: Based on your answers and Part I, with using the BCAT, please indicate if the patient DOES have capacity or DOES NOT have the capacity to make the decision at hand.

☐ DOES have the capacity to make the decision. Must answer "YES" to 1, 2, 3, AND 4.

☐ DOES NOT have the capacity to make the decision. Any "NO/NOT SURE" answer on 1, 2, 3, or 4.

Comments: _____

_____

_____

_____

[This query section follows every case in the original BCAT. The text of this appendix continues next page.]

Case 2: A 74-year-old married woman with a history of transient ischemic attacks and peripheral vascular disease is admitted to the orthopedic service after a fall at home that yielded a fractured hip. An Open Reduction Internal Fixation (ORIF) has been recommended for treatment. The patient has been amenable to the pre-operative work up, and appears to visit appropriately with family in the hospital. Three hours after being provided information about the indications, risks, benefits, and alternatives to the surgery, the patient is asked to describe in her own words her understanding of the procedure. She acknowledges, "I need to get my hip fixed by the surgeons." Asked what that might entail, she says, "I have no idea what they do." Pressed further for basics on the procedure, she says, "I just hope they decide to do it in the operating room instead of my hospital room, since there are a lot of germs in here. And they better put me out for it, I am nervous. I don't know what they are going to do. I just want to be out for it." Does this patient have capacity to consent to hip surgery?
[See case 1 for the queries that followed this case in the BCAT.]

Case 3: A 62-year-old woman with a history of atrial fibrillation on warfarin therapy presents to emergency department at her own initiation with bright red blood per rectum. An initial complete blood count (CBC) reveals severe anemia, prompting admission to the medical service for sequential CBCs and a colonoscopy. A second CBC six hours later demonstrates a continued drop in hemoglobin and hematocrit. Ten hours later, when the doctor is called due to the patient's fainting from symptomatic orthostasis, the patient requests discharge from the hospital, saying she has important business to manage at home. Asked specifically about this "business," she replies, "I need to meet the cable guy, and you know how difficult they are to schedule." An intern had informed her that her "blood counts had stabilized," after a third hemoglobin/hematocrit demonstrated no significant change from the second (Hgb/Hct = 6.8/28). Previous records indicate no anemia at baseline. The doctor asks the patient to stay for a colonoscopy, scheduled for later that morning, pointing out that there could be "an internal bleed that we need to find and correct." The patient acknowledges the possibility, but states, "I don't think I was bleeding, I'm pretty sure it was a mistake in the tests. They make mistakes, you know, and I don't think my blood tests are that bad. Doctors tend to exaggerate things so they can do more tests and make more money. I'm certain there's nothing seriously wrong; if there is, I can always come back." Does this patient have capacity to elect to leave against medical advice?
[See case 1 for the queries that followed this case in the BCAT.]

Case 4: An 84-year-old married woman without a psychiatric history, but with a recent diagnosis of dementia of Alzheimer's type, is brought in by her husband for shortness of breath and reduced exercise tolerance. Her hospital work up reveals a severely calcified aortic valve, prompting cardiothoracic surgery to recommend transthoracic aortic valve replacement. The surgeon provides the relevant information on the operation to the patient, to which she said, "I'd like to think about it." Several hours later, when asked about her decision, she politely declined, saying, "Well, it's a risky surgery, especially for someone my age, and my husband would prefer it if I died anyway." Further evaluation reveals a belief the patient has maintained for the last six months that her husband has been unfaithful to her, carrying on an affair with a 65-year-old woman. The patient is able to articulate the reason she needs the procedure, the expected benefit, the major risks, and even a basic description of the technique to be used. During the conversation, she intermittently glares at her husband, and says, later, "I might as well not talk about this matter any longer and just give him what he wants." This statement prompts her devoted husband of 47 years to ultimately throw up his hands in disgust and leave the room. Does this patient have capacity to refuse the recommended cardiac surgery?
[See case 1 for the queries that followed this case in the BCAT.]

Case 5: A 56-year-old male with a known history of schizophrenia and multiple psychiatric hospitalizations presents to the emergency department with weight loss, nausea, and vague complaints of abdominal pain. The admission work up reveals pancreatic cancer. The patient is offered palliative radiation therapy, with its indication, benefits, and limitations explained. Asked to articulate his understanding of the proposed treatment, the patient replies, "Oh, I know my predicament. I'm going to die from this cancer. The radiation may help me feel a little better, and eat a little better, but in the end the result will be the same. I've made my peace with this life and am ready to go." He then thanks the house officer for her time, and proceeds to ask his nurse about proper attire for the "xenon show tonight." Does this patient have capacity to refuse palliative radiation therapy?
[See case 1 for the queries that followed this case in the BCAT.]

Case 6: A 77-year-old married female with chronic obstructive pulmonary disease and documentation of dementia in past discharge summaries is admitted to the hospital for bilateral pneumonia. Review of the chart from this hospitalization reveals a pattern of increasing confusion in the evening, one such episode resulting in the provision of a prn antipsychotic for tranquilization. A pro-active house officer attempts to discuss do-not-resuscitate (DNR)/do-not-intubate (DNI) status with the patient on the morning of hospital day 3. The patient is pleasant and engaged, stating, "I've had a lot of life in my years, and I certainly wouldn't want to spend my last ones on a breathing machine, because that's no way to live." In further discussion, the patient indicates, "I wouldn't want those shock things on my chest either. If my heart stops, just let me be." In light of episodes of agitation and confusion described in the chart, the house officer then conducts a brief cognitive exam. This assessment reveals that the patient is disoriented (wrong hospital name, wrong location, month off by two, and

year off by one), and does not recall that she has been treated with an antibiotic. After the cognitive assessment, the patient is asked once again about DNR/DNI status. The patient is consistent and states she would not want to be on a "breathing machine or be shocked." Does this patient have the capacity to initiate DNR/DNI status?
[See case 1 for the queries that followed this case in the BCAT.]

Case 7: A 57-year-old male actor with no significant medical history presents to hospital with anorexia, weight loss, and marked change in bowel habits. Work up reveals stage IIb colon cancer, with histology and local invasiveness that make this particular disease riskier for recurrence and metastasis. Recommended treatment includes surgery to remove the cancerous tissue, along with adjuvant chemotherapy due to the high-risk nature of this tumor. The patient agrees to the surgery, but flatly refuses the adjuvant chemotherapy. He states that he understands the cancer diagnosis, as well as "the need for surgery to cut it all out." He says, "I get that you-all think this type of cancer is likely to return, but I don't think so. I've always been lucky in life, and I have every reason to think I will be here too." He also cites the likelihood of hair loss during the chemotherapy as a "deal-breaker. . . . I'm on-screen for a living, and need my hair to work." Does this patient have capacity to refuse adjuvant chemotherapy?
[See case 1 for the queries that followed this case in the BCAT.]

Case 8: A 72-year-old African-American male with a documented history of diabetes mellitus, cerebrovascular disease, and smoking is admitted to the hospital for work up of unstable angina. Cardiac catheterization is recommended to elucidate the nature and extent of likely coronary artery disease. The patient refuses to consent to catheterization, saying, "I'll take any medication or an IV or otherwise to get me better, but goodness knows what'll happen to me in here if I'm sedated. I already waited seven hours in the emergency room for a bed up here." Further interview reveals that the patient understands that his chest pain could relate to "blocked arteries in my heart," which is "a real possibility due to my diabetes and smoking." He understands the nature of the catheterization, as well as risks, benefits, and potential consequences of refusal. Asked why he nevertheless won't consent, the patient replies, "I'm just a little uneasy about a procedure with sedation. Bad things have happened to folks that look like me when they're sedated in hospitals. I want to go the blood thinner route and take my chances." Does this patient have capacity to refuse cardiac catheterization?
[See case 1 for the queries that followed this case in the BCAT.]

Case 9: An 84-year-old female who recently moved to an assisted living facility in the community presents to the hospital with lightheadedness and increasing lower extremity edema. The work up reveals severe mitral valve disease, with valve replacement surgery as the treatment plan. The patient quickly agrees to the procedure, saying, "Yes, something needs to be done, I can't walk around with my ankles this big," and then begins laughing raucously. The house officer entered her room 10 minutes after she signed the consent for surgery to discuss an unrelated health matter. At that time, the trainee noted that the patient was inappropriately jocular and confused. The patient knew she was in hospital for "my elephant ankles" and that "something is dreadfully wrong with my ticker!" She noted, "I think I'm going to have surgery, but who knows with doctors these days, they might just change their mind." She was unable to describe even basics regarding mitral valve replacement or what the surgery would entail, only insisting, "I should definitely have it." Did this patient have capacity to consent to the recommended cardiac surgery?
[See case 1 for the queries that followed this case in the BCAT.]

Case 10: A 70-year-old White male with known diabetes mellitus, coronary artery disease, and spinal stenosis is admitted to the hospital with swelling of hands and legs. Evaluation reveals an extremely elevated serum creatinine of 5.2 and limited urine output, even with Foley catheter placement. Urgent dialysis is recommended. The patient is lethargic, even intermittently sedated. When awake, however, the patient clearly and consistently refuses dialysis, stating, "I've been through enough with all my illnesses, and I'm just tired." He expresses an understanding of the treatment and its risks. Furthermore, he is able to explain that death is the likely outcome for such treatment refusal, and that hemodialysis could forestall this outcome. Does this patient have capacity to refuse hemodialysis?
[See case 1 for the queries that followed this case in the BCAT.]

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Meaningful Use of Electronic Health Records for Quality Assessment and Review of Clinical Ethics Consultation

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ABSTRACT

Evolving practice requires peer review of clinical ethics (CE) consultation for quality assessment and improvement. Many institutions have identified the chart note as the basis for this process, but to our knowledge, electronic health record (EHR) systems are not necessarily designed to easily include CE consultation notes. This article provides a framework for the inclusion of CE consultation notes into the formal EHR, describing a developed system in the Epic EHR that allows for the elaborated electronic notation of the CE chart note. The implementation of the "meaningful use" criteria for EHR, mandated by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, requires that health professionals meet certain standards for quality, efficiency, and safety, all of which overlap with the goals of standardization, peer review, and quality improvement within CE consultation.

INTRODUCTION

Clinical ethics (CE) consultation is increasingly available in academic medical centers and community hospitals as a support for difficult and conflicted decisions in healthcare. There is a growing consensus that CE consultation demands peer review and quality improvement. One process commonly utilized to assess a CE consultation's effectiveness and outcomes is a review of the chart note. The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 set the electronic health (EHR) record as one of the required benchmarks for excellence, mandating that eligible healthcare professionals and hospitals demonstrate "meaningful use" of EHR systems by meeting certain objectives.[1] To our knowledge, most EHR systems do

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not contain a template for CE consultation chart notes; in order to incorporate CE consultation notes into the EHR, CE consultants must consider how to incorporate valuable consultation information and analysis into an EHR system. Thus, if CE consultation charting is to be integrated into the EHR, CE consultants must create a platform to allow electronic recordkeeping.

Different medical facilities have contracted with various software companies to provide templates and systems for an electronic patient record and its subsequent review. One such company is Epic, an EHR software purveyor that purportedly manages 54 percent of patient medical records in the United States.[2] New York City Health and Hospitals Corporation (NYC H+H) is one entity that uses Epic and does not have a proprietary interest in the company. Other frequently used EHRs in the U.S. include Cerner PowerChart, AllScripts Professional, NextGen, and athenaClinicals.

The authors constructed a CE consultation electronic charting system using the EHR platform that was available to them. The goal was to incorporate available Epic functionalities to support, enhance, and provide for peer review for the work of CE consultants within the NYC H+H system. Documentation of an individual patient's CE consultation in the formal health record is one standard for medical centers to meet that is recommended by the American Society for Bioethics and the Humanities.[3] The template and materials created for the NYC H+H system could easily be applied to other medical centers around the country, regardless of whether they use Epic as their EHR platform. This platform can be used to standardize CE consultation recordkeeping nationally, as various hospitals have different CE consultation policies.

This article, using a de-identified case example, shows how the CE consultation chart note may be constructed in an EHR system to provide in-depth knowledge about the case, evaluation of the case's ethical issues, peer review as the basis for quality improvement, and an effective platform for statistical analysis. Interwoven into the article is a description of the growth of EHR and how meaningful use criteria dovetail with the goals of CE consultation.

A MODEL FOR THE CE CONSULTATION NOTE IN THE EHR

NYC H+H developed a robust system for requesting and documenting the CE consultation process in Epic. When an ethical issue arises with a patient's care, the treating physician can order a CE consultation as for any other medical specialty. The CE consultant will then see the request and can respond to it in a timely fashion. As one of HITECH's goals of "meaningful use" of EHR systems is the facilitated sharing of health information, this system allows CE consultants to access patients' information quickly and efficiently, facilitating more immediate meeting between the CE consultant and the patient.

Unlike other specialties, a CE consultant records notes after a meeting, not during a patient visit. The purpose of this method of note taking is to ensure the consultant's focus is on the patient, family members, and careproviders at all times. The CE consultant provides a listening ear and gathers the ethically relevant medical information and ethically relevant social history, which will be crucial for considerations of ethical issues and subsequent analyses. After a visit, and at any subsequent meetings with the patient's healthcare team, the consultant records the visit and the resulting conclusion of the consultation. Prior to the introduction of EHR, recording a single patient's visit might take hours, often resulting in illegible handwritten notes. Handwritten notes proved problematic during chart reviews, as the reviewing consultants spent valuable time deciphering handwriting. More importantly, long, discursive, and analytic written notes are likely to be unread by staff who were not involved in the consultation.

NYC H+H's system is a streamlined method of recording CE consultation notes that has the potential to save the consultant time and more clearly communicate to the patient's healthcare team the ethical issues at stake. Chart notes require the following fields:

1. Ethically relevant medical information
2. Ethically relevant social history
3. The ethical issues identified and analyzed
4. A recommendation and a beginning notation of whether the patient was engaged in the discussion, with a reason if the patient was not engaged in the discussion.

We will present a complex case and how to chart it using the NYC H+H chart note template.

THE MANDATE FOR EHR ADOPTION AND "MEANINGFUL USE" CRITERIA

Before we present a case demonstrating how the CE consultation note can be implemented into the EHR, we would like to discuss the important "meaningful use" criteria that guide work on the EHR.

The central purpose of CE consultation in healthcare is "to improve the process and outcomes of

patient care by helping to identify, analyze, and resolve ethical problems."[4] CE consultation constitutes a maturing intervention, and provides a vital service to patients, their family members, and the healthcare team when difficult, emergent, and often conflicted decisions regarding a patient's course of treatment must be resolved. Although there are stipulated competencies that CE consultants must meet, there is currently no agreement in CE consultation scholarship on standards of practice, acceptable or ideal qualifications for practitioners, or valid and reliable measures to rate the quality and effectiveness of CE consultation.[5] While this discussion about CE consultation is focusing, a new factor—the adoption, implementation, and expansion of EHRs—will further illuminate the issues. Thus, it is necessary to evaluate existing EHR systems that incorporate CE consultation notes and evaluate how meaningful use criteria can align with the goals of CE consultation.

In the past decade, EHR systems have begun to transform clinical care, as healthcare practitioners shift their recordkeeping from paper to electronic systems. There have been noted improvements in patient care as EHR becomes the standard, including improved quality of care, reduction in medical and prescription error, enhanced operational performance, increased regulatory compliance, reduction in medical costs, and improved population health outcomes.[6] The HITECH Act, signed into law by President Obama as part of the American Recovery and Reinvestment Act of 2009 (ARRA), is the largest U.S. initiative to date designed to encourage the widespread usage of EHR. It encourages careproviders to implement EHR in a "meaningful" way.[7] The Office of the National Coordinator for Health Information Technology has established criteria for what is considered "meaningful use" of EHR: improve quality, safety, and efficiency; reduce health disparities; engage patients and families in patient care; improve care coordination among careproviders; and ensure the privacy and security of protected health information.[8] All of these elements are relevant to the work of CE consultation.

CASE EXAMPLE: AN EPIC CHART NOTE

Consider the following CE consultation chart note provided in the Epic system of a large metropolitan hospital. Or, as Rita Charon might assert, consider this story of this patient, family, and the healthcare team as told in the CE consultation note in the medical chart.[9] (The following chart note has been anonymized, and all relevant social and demographic data have been altered. The original composers of the chart note, who agree that the patient is not identifiable, have revised it.)

Reason for Consultation

The patient is 68-year-old Hispanic female with dementia and multiple medical problems who was transferred from a nursing home with dry gangrene of right foot, for evaluation for possible amputation. The patient consistently refused amputation and this consultation was called to evaluate that refusal.

Ethically Relevant Medical Facts

The patient has multiple medical problems: diabetes mellitus, hypertension, a past cerebrovascular accident, hypercholesterolemia, sinus node dysfunction, left hemiplegia, dementia, dysphagia, peripheral artery disease, bilateral leg ulcers, pneumonia, cataract, hepatitis, pressure ulcer. Her medications include: nifedipine, metoprolol, hydralazine, divalproex, citalopram, omeprazole, insulin detemir, insulin aspart, and aspirin.

Ethically Relevant Social Facts and Decision History

Patient lives in nursing home, was born in Colombia, reports finishing high school. Never married, has no children. Has 2 sisters (both live in Georgia) who come to visit her once in a while.

I spoke with her brother Robert yesterday, who lives in New Jersey. He stated that he is not her closest sibling, but still he participated and said that he would talk to the sisters in Georgia. He would not give consent for the patient, since he felt he was not called with details pertaining to the surgery by the surgical doctors. He clearly stated that his sister's—the patient's—decision has to be taken in the contexts of her "limited ability in mental function."

Patient was admitted for above problem in September and refused surgery. She was seen by Psychiatry service shortly after admission. Initially not cooperating, but with second visit the consulting Psychiatrist documented her saying that: "she is in the hospital because she needs help because there is something wrong with her feet and doctors know best." She reported being "scared" because "they are going to do surgery." She also said—as documented, that she "will support the doctors in whatever treatment they think is better" because she wishes to get better and live.

Eventually did agree to have the surgery. After w/up was completed she was taken to holding area on Sept 10 but then she refused the surgery. Since she was stable medically, she was sent back to the nursing facility.

On November 10 was readmitted. Examination determined that the gangrene seemed worse. But also patient "confused and obtunded" as noted by Psych consultant who was recalled to assess patient's decisional capacity. She was deemed not to have capacity. Ethics was called yesterday to help create best care plan.

When approached at first, patient did not want to talk. She covered her head and said she wants to sleep. We came back about 1 hour later and found her in holding area just about to go to OR for the amputation. Patient now was willing to talk and said that she is being forced to get the surgery. That the doctors want to

cut her leg and she will not let them. She said that to do the operation the doctors need to get her permission and she is not going to give it. She volunteered also that she would rather die than let the leg be cut.

The Surgery attending was present and we have talked to the patient together. We advised on postponing the surgery and contacting the family. Patient had fever last night and the surgery soon may turn to be emergent and possibly lifesaving if she gets septic. She seemed quite understanding of what is proposed and clear in her decision today but considering her prior and quoted above words, more discussion has to take place. It is possible that she has limited trust with the team and being left alone to make this decision, withdraws. She may have limitations in decisional capacity due to her underlying dementia.

The Attending was planning to contact family. We'll try to arrange a meeting with the local brother and conference call to the sisters in Georgia.

Discussion Next Day

I met with the patient today and talked again about patient's wishes regarding the surgery. She did not change her mind. She said that she wants to go back to nursing home. She talked to me about her strong spiritual beliefs, she wanted to be taken to church. We spoke a bit about interpreting beliefs. "God will save me," said the patient. I have tried to point that this may happen by having the surgery so the infection will not spread, but patient said, "I know about the gangrene" and kept to her decision not to allow for the leg to be cut. I asked hospital priest to arrange for spiritual support. She also said, "You are trying to help me."

Ethical Analysis: Decision-Making Capacity

Determining whether a patient has the capacity to make medical decisions is often a key in a CE consultation. Decisional capacity is not a legal determination, but a clinical one that should be made by the attending physician who has the primary responsibility for treatment and care of the patient. Best practice would have that physician confer with the healthcare team who have interacted with the patient over time. **Capacity refers to the patient's ability to perform a set of cognitive tasks, including:**

- **Understanding and processing information about diagnosis, prognosis, and treatment options**
- **Weighing the relative benefits, burdens, and risks of the therapeutic options**
- **Applying a set of values to the analysis**
- **Arriving at a decision that is consistent over time**
- **Communicating the decision** [Bolded text is prewritten text provided in the chart note program—see figure 3.]

In this case the patient was first held to be without decisional capacity. However, on subsequent admissions, she was consistent in her refusal of care when not pushed to agree. Her position was also supported by her family, who were contacted by the care team and were aware of her medical situation and its possible consequences.

In CE consultation, consistency over time can sometimes be as powerful as demonstrated capacity. This is such a case. In addition, the family is supporting the patient and does not want to go against her "spoken choice," that is, against the values being articulated even if by a decisionally compromised patient.

Then there is the matter of supporting refusal until the case develops into an "emergent" intervention, which, for some care-providers, permits an end to respecting the refusal. Ethically, depending on evolution to "emergent" does not negate prior accepted refusal.

Finally, in this analysis, the opposing position would be one that argued that the action taken should be one in the "best interest" of the patient and might push her to agree to surgery. However, **this standard is employed when there is no knowledge of a particular patient's prior wishes or inferred wishes, it is primarily an impersonal standard. In the absence of such particularized knowledge, the best interest standard considers what would be most likely to benefit or promote the well-being of a hypothetical reasonable patient in the same circumstances as those of the patient.** [Bolded text is prewritten text provided in the chart note program—see figure 3.]

But this is NOT a patient whose values and positions are unknown. What is not known is whether these spoken choices actually reflect the adequate evaluation and assimilation of the serious medical facts that predict a likely negative outcome for the patient.

Finally, even though her family is in agreement with the patient's decision, it would have been prudent to involve them more quickly in the discussions.

Recommendation

This is a troubling case, as the patient is refusing surgery for increasingly serious gangrene of the right leg. However, she has been consistent in refusing the surgery, and, at times, seems to indicate some understanding or insight. However, it is by no means certain that she truly understands. In addition, her siblings, who are moderately involved, support her decision. We are faced with suggesting the "least/worst" solution, which is to respect the "spoken choice" of the patient, despite our uncertainty of the level of understanding that undergirds that statement. That is ethically problematic, but less so than imposing surgery over her consistent refusal and the refusal of her family.

Follow Up

Today patient told me she was going to nursing home; she was content. I called her brother Robert again. He explained Attending Dr. X called him and his sister Cecilia in Georgia. They all agreed patient seems to have consistent, clear wish to not have the amputation. She seems to well understand the consequences, including dying from infection, she repeated to me—"I am ready to die." They agreed doing the surgery would go against patient's will. Robert appreciated our concern and effort in this complicated situation. The patient will be transferred today back to nursing home. I reassured him and his sister Cecilia we will support them.

MEANINGFUL USE CRITERIA AND CE CONSULTATION

Each criterion for meaningful use listed in the section, "The Mandate for EHR Adoption and 'Meaningful Use' Criteria," above, has the potential to support and expand the CE consultation field. The first criterion aims to improve healthcare quality, safety, and efficiency. Those three characteristics are infrequently applied to CE consultation, but are key to successful consultation. If CE consultations are conducted poorly, the recommendations of a CE consultant can advance her or his philosophical and preordained positions and defeat the interests, values, and moral perspectives of the patient and family. CE consultation, if done well, can enhance the ability of patients, careproviders, and family members to arrive at ethically compatible, medically effective care planning that addresses the idiosyncratic values of the participants.

Consider the case presented above. The options, in the abstract, would be:

1. To determine that the patient did not have the decisional capacity to understand that the surgery would be lifesaving, which would allow a court to override her "spoken choice" and order amputation of her leg.
2. To deem the patient decisionally capable and thus to respect her refusal, leaving her careproviders in fear of "abandoning" the patient to her dementia as the toxicity of the gangrene overwhelmed her.

However, in this case, the CE consultant was able to solicit family members' confirmation for the position of the patient and enable collective support for her refusal of care. The interaction of a CE consultation is generally a series of discussions; thus, a most effective way to review the quality of a CE consultant's intervention is to review the chart note that documents the discussions and actions. The notes documented in the EHR that are legible and consistent can be assessed in a peer-review system that will facilitate quality improvement.

The intervention in this case was to provide facts and analysis that supported the rather controversial decision of a decisionally compromised patient to refuse what would likely be considered lifesaving care by medical professionals. Without that consultation and analysis, it would likely (even though prediction in clinical ethics cases is always uncertain) be the case that action would have been taken legally and medically to undercut the patient's decision.

The CE consultation notes also address safety concerns. Most often, the literature on EHR implementation describes safety as the avoidance of medical errors, particularly with prescriptions. CE consultations can avoid ethical errors that are quite as serious. When there is miscommunication among healthcare providers relating to a complex case, there is a risk of imposing medical solutions that are not in accord with the moral choices and health preferences of the patient and the patient's family. Electronic notation requires an articulation and analysis of the values and preferences of the patient and family members in the real time of the consultation. In the NYC H+H schema, it also requires the description of ethically relevant medical and social facts on which to base the ethical analysis. EHR demands prevent the CE consultant from making an ethical mistake by imposing an unwanted or undesirable intervention on the patient or family.

The third and final concept addressed in the first meaningful use criterion is efficiency. In complex healthcare situations, efficiency means using time and effort in the most expeditiously way to solve a problem. CE consultation can be used to clarify the values and preferences of the patient and family, to identify hospital rules and policies that would be relevant to the case, and to use collected data to resolve conflicts about patient care. Using a standard Epic form for each CE consultation permits all members of the patient's healthcare team to access these data and circumvents the inefficient re-examination of issues in any case.

The second meaningful use criterion aims to reduce health disparities, which can be the result of the insidious operation of bias and prejudice among careproviders in any healthcare system. The CE consultation forms in the EHR require that the logic of the CE consultant's analysis be explained and documented. This explicit documentation works to combat the implicit bias that often leads to health disparities, particularly with patients in minority groups and those who are disabled. Engaging with individual patients and families is a core aim of CE consultation. This requirement supports the importance of documenting encounters in the CE chart, addressing ethical issues, and providing education about difference for the staff who read the note. Open discussion and analysis is the enemy of prejudice and disregard. CE consultations that are documented in the chart serve ti contest prejudiced notions about persons of color and those with disabilities by identifying the unique factors in each case.

Finally, the meaningful use of EHR requires that the privacy and security of patients be maintained.

Ensuring patients' privacy is outside the realm of the specific goals of CE consultation, but, like all healthcare providers, CE consultants are bound to uphold the privacy and security of patients' records. However, there is a skill to writing a CE consultation chart note that shares sufficient information on which to base the ethical analysis and recommendations and yet respects the patient's privacy and dignity. Occasionally patients have "secrets" that should not be shared. More importantly, respect for patients, family members, and careproviders should undergird every chart note.

PROCESS AND PRODUCT

Depending on whether the treating physician filled out some information during the CE consultation request, some of the ethically relevant medical information may already be filled in for the CE consultant in the chart note. Figure 1 shows the structure of the CE consultation note in Epic, with the relevant drop-down menus for data entry. While some fields, like "Ethically relevant medical information" and "Ethically relevant social history," require text entry, many fields offer a menu of choices. If a choice does not suit the reality, the CE consultant may choose an "Other" choice when appropriate and inject text.

FIGURE 1. Structure of the CE consultation note and description of data entry. Each heading represents a different section in the chart note the consultant must fill out after the initial patient visit.

[Date and time of response]
Ethics consult (check one response)
- Indicated
- Not indicated

Have you communicated with the patient (or if communication not possible) viewed/visited? (check one response)
- Yes
- No

Consultant's determination of decisional capacity
- Yes
- No
- Uncertain
- Unknown

Ethically relevant medical information
- [text entry]

Ethically relevant social history
- [text entry]

Consultant's determination of category of referral
- [see figure 2 for drop-down menu]

Ethical analysis
- [see figure 2 for drop-down menu]

Recommendation(s) in terms of ethics
- [text entry]

Number of meetings
- [see figure 4]

Nature of consult (choose one or several)
- Mediation
- Teaching
- Informational
- Policy interpretation
- Other [text entry]

In the line, "Consultant's determination of category of referral," NYC H+H's Epic system allows the CE consultant to first choose from a list of potential ethical issues, aimed at helping the consultant and medical team to quickly identify the issues at hand (see figure 2). In the next section of the chart note, the CE consultant can insert one or more prewritten analyses designed by the clinical ethics team at NYC H+H in a drop-down menu (see figure 3). Each paragraph in the prewritten analyses corresponds to a topic from the category of referral list shown in figure 2; these analyses were written to generally explain the nature of common ethical issues that arise in patient care.[10] The CE consultant can choose to edit or excerpt the analysis as he or she sees fit; the CE consultant is not locked into the text of the analysis. The goals of the analyses are to serve as guidelines and reference points for the CE consultants as they act to implement a consultation, and as text to be edited for the chart note. As part of the chart note, these texts act as teaching tools for healthcare providers so they can better understand how ethical issues apply in a particular patient's case.

In the chart note for the case we presented above, the consultant chose "Decision-making capacity" as the primary ethical issue rather than "Consent to and refusal of treatment." Consider whether this was the correct focus by comparing the text on capacity, set in bolded text in the "Ethical Analysis" section of the case, with another of the prewritten analyses designed by the CE team, "Refusal of treatment":

> Refusal of recommended treatment should initiate a discussion about the reasons for the refusal. The patient might not understand the nature of the treatment that is being proposed and its potential risks and benefits may have certain fears relating to the treatment that can be addressed, or may have a treatable depression. Because of their profound implications, refusals of life-sustaining treatment in particular should receive heightened scrutiny as should decisions to accept high-risk life-sustaining

> treatment. In general, in the case of treatment refusal, special attention should be given to the adequacy of the information presented and the quality of the explanation, possible language or cultural barriers to understanding, and the patient's capacity and appreciation of the consequences of forgoing treatment.

Because each CE case is unique, there is a risk that the EHR could become depersonalized and homogenized as a "copy and paste" exercise that appears virtually the same from one patient to another.[11] To ensure that the CE consultant is able to construct a narrative as he or she sees fit for an individual patient, the prewritten ethical analysis paragraphs can be inserted into the chart note, either verbatim or as altered text. This compromise between adoption and free-form creation allows the CE consultant to create efficiently while personalizing the chart note.

In this story, as told in the chart note, a psychiatrist initially judged the patient not to have decisional capacity, causing the primary care physician to request a CE consultation. The psychiatrist saw a patient refusing amputation for her gangrenous right leg, which a surgeon had deemed medically necessary to save her life. The first ethical issue, therefore, was whether the patient possessed decision-making capacity as described in the paragraph on that subject.

The CE consultant was clearly concerned about the patient's decisional capacity, given her dementia and the quality of her initial decision. However, because the patient was able to exhibit consistency over time regarding her desire not to have the surgery, the CE consultant offered an alternative analysis to the discussion of capacity, with which the chart note begins, "In CE consultation, consistency over time can sometimes be as powerful as demonstrated capacity. This is such a case. In addition, the family is supporting the patient and does not want to go against her 'spoken choice,' that is, against the values being articulated, even by a decisionally compromised patient."

This case demonstrates that judging decisional capacity is a complex matter. From a psychiatric standpoint, it appears irrational that one would refuse surgery to treat an infection that could cause death. Thus, the patient's initial assent to surgery, followed by a refusal and admission that she would "rather die" than undergo an amputation, appears to violate the assumed decisional norm. Complicating the matter is the finding that the patient has dementia, usually deemed capable of destroying decisional capacity. But further interaction by the CE consultant with the patient and family revealed that

FIGURE 2. Categories of referral and headings for ethical paragraphs. This is a complete list of categories in a drop-down menu from which a consultant can choose. In the subsequent section in the chart note, each category has a pre-written paragraph summarizing the nature of the ethical problem.

Advance directives
Allocation of scarce resources
Assent and consent
Best interest standard
Brain death and reasonable accommodations
Challenging families
Challenging goals of care
Communication
Confidentiality
Conscientious objection
Consent to and refusal of treatment
Cultural/religious issues
Cultural values and treatment
Dealing with the adolescent patient
Decision about artificial hydration and nutrition
Decision-making capacity
Decision maker identification
Decision making in the neonatal intensive care unit
Disagreements between patients and family
Disagreement between staff and patient/family
DNR orders
Doctrine of double-effect
End-of-life balance of acute and palliative interventions
Failure of the medical team to assume responsibility for difficult choices
False choices
Informed consent
Informed consent as a number of requirements
Mediation
Medical futility
Moral distress
Organization ethics
Palliative care
Patient autonomy
Quality of life
Religious values and treatment
Shared decision making
Sharing the burden of responsibility
Substitute judgment
Therapeutic exception
Truth telling
Withdrawing and withholding treatment
Other(s)

the patient's preference to refuse surgery was consistent over time and was supported by her family.

Thus, the chart note analyzes the concept of decisional capacity in two parts: (1) by introducing the

FIGURE 3. Full texts of paragraphs on decision-making capacity and best interest standard from the NYC H+H EHR chart note program

16. Decision-making capacity. Determining whether a patient has the capacity to make medical decisions is often a key ingredient of a clinical ethics consultation. Decisional capacity is not a legal determination but a clinical one that should be made by the attending physician who has the primary responsibility for the treatment and care of the patient. Best practice would have that physician confer with members of the healthcare team who have interacted with the patient over time. Capacity refers to the patient's ability to perform a set of cognitive tasks, including:

- Understanding and processing information about diagnosis, prognosis, and treatment options
- Weighing the relative benefits, burdens, and risks of the therapeutic options
- Applying a set of values to the analysis
- Arriving at a decision that is consistent over time
- Communicating the decision

Having capacity enables an individual to make decisions; it does not obligate him or her to do so, and in fact a person with decisional capacity may waive the right to make decisions or confer this right on others.

It is an established principle of law and ethics that adults who have the capacity to make their own medical decisions should be permitted to do so. Not to give them the opportunity to make their own decisions is a violation of their right to autonomy.

Decisional capacity is decision specific, that is, it varies according to the complexity and seriousness of the decision at hand: more complex and more weighty decisions require a greater degree of decisional capacity than do less complex and less serious ones. The appointment of a healthcare agent, for example, requires only a fairly low level of decisional capacity, whereas deciding whether to have a complicated surgical procedure requires considerably more. In addition, decisional capacity is not always clear-cut or necessarily constant. In some cases, there may be no definite answer to whether the patient has the capacity to make a particular decision. And depending on their age, cognitive abilities, clinical condition, and treatment regimen, patients may exhibit fluctuating capacity. For example, elderly patients often exhibit greater alertness, clearer reasoning, and better communication earlier in the day. Drug interactions can also cause a temporary loss of capacity.

4. Best interest standard. Frequently treatment decisions must be made for patients who lack capacity and cannot decide for themselves. These may be persons who were formerly but are no longer capable of making decisions, or individuals, like newborns or severely developmentally disabled persons, who never had the opportunity to form values or preferences. The standards for healthcare decisions for patients who lack capacity give preference to the patient's voice as the central and most widely accepted source of authority. In some cases, the decision maker may rely on the prior stated wishes of the patient or, if these are not known or were never articulated, the inferred wishes of the patient. But when neither is possible, the decision maker must rely on a best interest standard. This standard requires an objective assessment of the relative burdens of benefits of available treatment options.

Because this standard is employed when there is no knowledge of a particular patient's prior wishes or inferred wishes, it is primarily an impersonal standard. In the absence of such particularized knowledge, the best interest standard considers what would be most likely to benefit or promote the well-being of a hypothetical reasonable patient in the same circumstances as those of the patient. Any additional information specific to the particular patient being treated might also contribute to an assessment of what is in his or her best interest.

In assessing best interest, both the outcome and the probability of achieving it for different treatment options should be considered. In the clinical setting, the best interest standard considers mitigating pain and suffering, prolonging life, restoring and enhancing comfort, and maximizing the potential for independent functioning. In all cases where this standard is invoked, best interest should be determined as far as possible from the perspective of the patient, not the decision maker. A life that may be unacceptable to the decision maker may be acceptable to the patient, and it is the latter standpoint that the decision maker should adopt.

The [New York State] Family Health Care Decision Act (FHCDA) provides for this as follows: The surrogate must make healthcare decisions in accordance with the patient's wishes, including the patient's religious and moral beliefs. If the patient's wishes are not reasonably known, and cannot with reasonable diligence be ascertained, the surrogate makes decisions in accordance with the patient's "best interests." An assessment of the patient's best interests shall include:

- Consideration of the dignity and uniqueness of every person
- The possibility and extent of preserving the patient's life
- The preservation, improvement, or restoration of the patient's health or functioning
- The relief of the patient's suffering
- Any medical condition and such other concerns and values as a reasonable person in the patient's circumstances would wish to consider.

In all cases, the surrogate's assessment of the patient's wishes and best interests must be patient-centered. Healthcare decisions must be made on an individualized basis for each patient and must be consistent with the values of the patient, including the patient's religious and moral beliefs, to the extent reasonably possible.

concept with a definition and analysis written by experts in the CE consultation field, followed by (2) a further explication of how this case demonstrates that consistency in spoken preferences, over time, with support from family members who know the patient's preferences intimately, are sufficient to allow the patient's preference to be respected. Note, however, that a CE consultation note is performed as a consultation to the attending physician, who must ultimately make the decision.

The prewritten ethical paragraphs (example are presented in figure 3) are valuable because they allow for consistent and precise definitions of terms like "decisional capacity" in the medical realm. Combined with the CE consultant's expertise and ability to read the notes before a consultation and to edit the text in the chart note, the EHR system in Epic allows for both consistency of terms and the construction of an individual patient narrative. However, if used without understanding, the "cut and paste" process could result in sloppy thinking, that could result in inappropriate recommendations.

Additionally, the CE consultation note in the EHR allows for the automation of valuable data that can be used for research. Figure 4 shows the type of data that can be entered for each individual CE consultation. Epic can automatically aggregate these data totals, which can help an organization to determine how many and what types of CE consultations take place in a given period of time. As CEC evaluation lacks quantitative data in many circumstances, this data entry and subsequent automated totals will help leaders in the CE consultation field make quantitative determinations regarding the use of CE consultation at a particular medical center.

BENEFITS AND DRAWBACKS OF CEC IN EHR

Notably, the aims of CE consultation and the meaningful use of EHR overlap with the ultimate goal of improving patient-centered care. But CE consultation notes in the patient chart have not yet been implemented into most EHR systems, like Epic or APeX, which are in use in the majority of U.S. healthcare centers and hospitals that have EHR systems. The recommendations by the National Working Group for the Clinical Ethics Credentialing Project urge that a formal note, using a standard format, be included in the patient's medical record.[12] Complicating the picture further, most bioethics professionals in the U.S. hold positions in academia or in large university settings, and there is a lack of specialized CE consultation professionals in smaller community hospitals.[13] Thus, it is difficult to obtain the most up-to-date information on CE consultation practices because due to a lack of CE consultation notes in formal EHRs.

EHR systems provide a number of functionalities that could be used in the CE consultation field to enhance the "meaningful use" of EHRs. The software tools that EHR systems provide aim to avoid medical errors, streamline communication within medical services and between hospitals, aid care-providers' decision making, and ease patients' access to medical records.[14] Research indicates that implementation of multiple EHR functions increased adherence to evidence-based clinical guidelines, improved efficiency, eliminated redundant medical tests, improved patients' safety, and reduced prescription error.[15] Organizationally, EHR can increase regulatory compliance and improve research capacity by providing a database of patients' records.[16] Similar benefits are expected for the CE consultant.

The Epic system implemented at NYC H+H allows any healthcare provider to request an ethics consultation. The CE consultant receives the request in real time, as any other medical professional would. The system assures the accessibility of the patient's ethically relevant medical information and ethically relevant social history, which are necessary for the education of the CE consultant prior to visiting the patient. Just as the CE consultants are able to access medical notes, physicians, nurses, and

FIGURE 4. Tools for data collection, based on number of encounters with patient and/or family. Because this section allows only nominal or numerical entry of data, CE consultants within a hospital system can gather de-identified data on a variety of measures that allow for the analysis of the CE consultative service as a whole.

Number of meetings with one individual (e.g., surrogate, family member, hospital staff member)
[Numerical entry]
Number of family meetings
[Numerical entry]
Number of clinician team meetings
[Numerical entry]
Additional research
[YES or NO]
Consultation with other ethics service staff
[YES or NO]
Ad hoc consult service meeting
[YES or NO]
Medical board, medical director, risk management, legal, clergy, hospital administration involvement
[YES or NO]

other healthcare providers are able to gain access to clinical ethics notes, including analyses and recommendations. The CE consultant may receive information about the patient's situation that has not been revealed to the physician during a consultation. Allowing this information—the patient's ethically relevant medical and social history—to be organized and readily accessible within an electronic system may improve the individual patient's hospital experience by educating the medical team.

Having focused on benefits above, a focus on the potential drawbacks of an EHR system, although troubling, might not have the same implications for CE consultation as for other medical services. Many potential problems are not as relevant to CE consultation: adoption costs, temporary disruption in work flow during adoption, the risk of violating patients' privacy, a loss in physicians' autonomy, or disruption in careprovider-patient relationships.[17] EHR systems eliminate many of these drawbacks for the CE consultant. First, CE consultants may gain additional autonomy as their time spent recording meetings decreases, allowing them more time to spend with patients, family members, or members of the healthcare team. Second, because CE consultants record their notes after patient visits and subsequent meetings, concerns regarding eye contact and patient interaction are largely eliminated. Finally, disruptions in work flow are to be expected initially, but investments in the system will ultimately continue to save time and will gather data about the CE consultation system that is invaluable. CE consultants are in short supply, so streamlining the recordkeeping process will allow consultants to spend more time working on ethical issues rather than on paperwork.

CONCLUSION

If CE consultation is to take its place among the regular interventions available in hospitals and in outpatient facilities, it must adhere to modern standards of medical practice. One growing practice is the use of the EHR as the basis for communication among staff and as a locus of quality improvement efforts. In this case, the fit between patterns of chart note practice and the demands of electronic efforts provide an excellent example of a "yin-yang" relationship. Ethics notes that are handwritten are far less effective for communication—and for any other purpose. A well-crafted CE chart note, in contrast, can help support a growing consensus about care, unify staff in dealing with patients and family members, and offer important supports for controversial decisions that might otherwise be troubling to careproviders. The use of the EHR is, therefore, a win-win for CE consultation services.

DISCLAIMER

The views, opinions, and positions expressed in this article are those of the authors and do not necessarily reflect those of their institutional affiliations. Neither the authors nor the public hospital system have any proprietary interest in Epic, nor were the authors responsible for choosing the system on behalf of NYC H+H.

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The Ethics of Bundled Payments in Total Joint Replacement: "Cherry Picking" and "Lemon Dropping"

Casey Jo Humbyrd

ABSTRACT

The Centers for Medicare & Medicaid Services has initiated bundled payments for hip and knee total joint replacement in an effort to decrease healthcare costs and increase quality of care. The ethical implications of this program have not been studied. This article considers the ethics of patient selection to improve outcomes; specifically, screening patients by body mass index to determine eligibility for total joint replacement. I argue that this type of screening is not ethically defensible, and that the bundled payment program as structured is likely to lead to unfair restrictions on who receives total joint replacements.

INTRODUCTION

Healthcare costs are increasing in the United States, from $1.4 trillion in 2000 to $3.2 trillion in 2015.[1] The continuing increase in healthcare costs has led policy makers to seek innovative cost-containment solutions.

The fee-for-service payment model has been targeted as a cause of the steady rise in healthcare spending because it provides an incentive to provide more, rather than better, care.[2] Although many physicians are offended by the notion that they might shirk their fiduciary responsibilities to patients in pursuit of profits, studies report that fee-for-service incentivizes physicians to provide nonbeneficial treatments, especially compared with other models of care, such as capitation.[3]

In an effort to address healthcare costs, a new care model has been introduced: bundled payments.[4] With bundled payments, a lump sum is paid for an episode of care, and the health system is then responsible for all follow-up care. If the care costs less than the bundle, the health system profits. However, if the costs are greater than the bundled payment, the health system absorbs the loss. The Centers for Medicare & Medicaid Services (CMS) has adopted the bundled payment model for numerous diagnoses and procedures, including replacement of hip and knee joints with artificial joints.[5] In theory, this is a rational solution because the bundled payment model eliminates the incentive to overtreat that is inherent in the fee-for-service model, while it emphasizes the coordination of postoperative care. However, the bundled payment model introduces new, perverse incentives: specifically, to select patients who are at low risk for costly intraoperative and postoperative complications.

In this article, I explore one particular mechanism for selecting patients: screening by body mass index (BMI). Bundled payments for total joint replacement, as currently designed, will likely lead

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to major restrictions regarding who has access to surgery. Total joint replacement is a high-value intervention that dramatically improves patients' well-being.[6] Modifications to the bundled payment structure should be considered to avoid systematic exclusion of obese patients.

THE UTILIZATION AND VALUE OF TOTAL JOINT REPLACEMENT

Total joint replacement is a widely implemented procedure. More than 7.5 million Americans are living with artificial joints, and more than one million total joint replacements are performed in the U.S. annually.[7] The frequency of the procedure continues to grow, with a 134 percent increase in the number of total knee replacements from 1999 to 2008.[8]

Hip and knee replacements lead to significant improvements in health-related quality of life.[9] The value of total joint replacement has been documented extensively. In countries that use quality-adjusted life years to calculate the value of a procedure, hip and knee replacements are considered high-value procedures and are commonly performed.[10] The author of a seminal study in the 1980s concluded that coronary artery bypass grafting was less cost-effective than total hip replacement, when assessed using quality-adjusted life-year value metrics in the United Kingdom.[11]

BUNDLED PAYMENTS

CMS is one of the major payers for total joint surgeries because of the age of most patients who require the surgery. The CMS website states: "Hip and knee replacements are the most common inpatient surgery for Medicare beneficiaries and can require lengthy recovery and rehabilitation periods. In 2014, there were more than 400,000 procedures, costing more than $7 billion for the hospitalizations alone."[12] To control costs, CMS began experimenting with alternative payment models,[13] culminating in the introduction of the Comprehensive Care for Joint Replacement Model. On 1 April 2016, CMS began mandating bundled payments for total joint replacement in 67 metropolitan statistical areas in the U.S.[14] Although all of the institutions within the captured region were required to be paid through the bundled payment program, there were no Medicare requirements regarding the design and implementation of the program.

The program was designed as a cost-saving and quality-improvement measure. If hospitals deliver care at costs below the bundled payment, they are allowed to keep the difference. The quality improvement is proposed to occur because hospitals will be incentivized to prevent costly postoperative complications such as pneumonia, deep vein thrombosis, and re-admissions. This contrasts with the fee-for-service model, in which complications could increase the hospital's profits because a prolonged stay and additional treatment increase the hospital's reimbursement.

Cost savings go directly to the hospitals. However, gainsharing agreements are possible between the hospitals and physicians, whereby the profits from decreased costs and increased profits are shared by both physicians and hospitals.[15] The relationship between physician compensation and hospital profit varies by individual contract.

To ensure quality improvement, CMS also created incentive payments for higher quality care.[16] Hospital care is assessed through two metrics. One metric is postoperative complications such as infections and readmissions within 90 days of surgery, and this is measured through risk-stratified complication rates using the National Quality Forum score. The second metric is patient satisfaction scores obtained through the Hospital Consumer Assessment of Healthcare Providers and Systems survey.[17] Some employment contracts tie the physician's compensation, at least in part, to the hospital's outcome scores.[18]

During the Comprehensive Care for Joint Replacement Model trial, CMS and orthopedic advocacy groups discussed adding risk stratification for patient morbidities to the payment structure because patients with pre-existing risk factors are likely to have more complications and incur higher health care costs than those without such risk factors. In the final rule, there was no substantial risk stratification. Instead, there were two tiers for payment based on the following diagnosis-related groups (DRGs): DRG 469 is joint replacement without major complication or comorbidity, and DRG 470 is joint replacement with major complications or comorbidities. These are broad categories, and Medicare is particular with its documentation of a major complication or comorbidity (MCC). Many diseases, which increase patients' complexity (for example, chronic kidney disease) are considered a complication or comorbidity (CC), not an MCC. A CC alone would not qualify a patient for DRG 470.

Before implementation of the planned payment structure, orthopedic surgeons expressed concerns. To quote: "Alternative payment models in total joint replacement incentivize cost effective healthcare delivery and reward reductions in length of stay

(LOS), complications, and readmissions. If not adjusted for patient comorbidities, they may encourage restrictive access to healthcare."[19] This has been described as physicians "cherry picking or lemon dropping" patients.[20]

COMPLICATIONS AND COSTS OF TOTAL JOINT REPLACEMENT IN OBESE PATIENTS

An extensive body of research compares outcomes after total hip and knee replacements on the basis of BMI. According to the Workgroup of the American Association of Hip and Knee Surgeons Evidence Based Committee, a BMI of 40 appears to represent an inflection point, above which patients have much greater risk of complications.[21] Compared with normal-weight patients, the risk of infection is twice as high in patients with a BMI of 35 to 39.9 and four times as high in patients with a BMI greater than 40.[22] Another study of patients who underwent primary hip or knee replacement found a 0.36 percent infection rate for patients with normal BMI, compared with 4.7 percent for patients who were morbidly obese.[23] Infection is a devastating complication in total joint replacement. Depending on the extent of the infection, the patient may undergo multiple revision surgeries, long-term intravenous antibiotic treatment, and multiple hospitalizations. Obese patients also have higher rates of hospital readmission compared with normal-weight patients. Reasons for readmission include infection, blood clots, pneumonia, and cardiac issues.[24] A study of patients who underwent total hip replacement found that the readmission rates were 13 percent among 39 morbidly obese patients and 2.7 percent among 186 normal-weight patients ($p = 0.005$).[25] Morbidly obese patients who underwent total hip replacement had higher odds of readmission (odds ratio = 1.74; 95 percent confidence interval: 1.25-2.43; compared with non-obese patients).[26] Another study found that in total knee replacement, the hazard ratio for readmission was 1.27 (95 percent confidence interval: 1.22-1.32) for morbidly obese patients compared with non-obese patients.[27]

The overall costs of joint replacement are higher for obese patients because of their higher rates of readmission and infection. Per five-unit increase in BMI beyond 30 kilograms per square meter, hospital costs increased by approximately $500 for primary total hip replacement,[28] and $250 to $300 for primary total knee replacement.[29] Therefore, a patient with a BMI of 45 would be anticipated to incur $1,500 in additional costs for hip replacement and $750 to $900 in additional costs for knee replacement, compared with costs for a normal-weight patient.

Surgery also takes longer for obese patients compared with non-obese patients. Reported increases in operative time range from 22 to 32 minutes for total hip replacement[30] and seven minutes for total knee replacement.[31] Although longer operative time is not a complication *per se,* it is important to understand that surgeons are paid by the number of surgeries they perform, rather than the duration of surgery. By performing longer surgeries on obese patients, surgeons ultimately lose money by decreasing the number of surgeries they can perform in a day.

These costs to the physician and treating institution, as well as the predicted increase in complications, create major disincentives to caring for obese patients. The higher rates of complications and readmissions associated with obese patients will negatively affect the treating institutions' CMS quality scores, with resulting decreased reimbursement for the hospital and possibly for the physician. Further, operative time is longer for obese patients compared with non-obese patients, and this may decrease the surgical volume of the surgeon. Finally, there is a documented increase in hospital costs for joint replacement surgery in obese patients, which will negatively affect the hospital's bottom line and any related gainsharing agreements with surgeons.

ETHICS, OBESITY, AND CMS BUNDLING FOR JOINT REPLACEMENT

Current CMS bundling policy creates major incentives for physicians to avoid performing total joint replacement for obese patients. The goals of bundled payments are to reduce costs and improve quality, not to limit access to joint replacement for certain patients. The American Association of Hip and Knee Surgeons encourages weight loss in obese patients before joint replacement surgery, but recommends against using BMI as a strict cutoff.[32] However, early evidence indicates that physicians are using BMI as a cutoff to determine whether a patient is eligible for total joint replacement. In a survey of 700 hip and knee surgeons, 62 percent reported using BMI scores as a cutoff for eligibility; there was no consistency to the BMI score used. Additionally, 42 percent of surgeons who used a BMI cutoff said they had done so because they were worried about their performance scores or those of their hospitals.[33] The question is: When, if ever, is it appropriate for surgeons to refuse to provide surgery to obese patients?

There are good *prima facie* reasons to do these surgeries, because people in pain will benefit greatly.[34] Therefore, refusing to perform the surgery requires justification. The stated reasons for not operating on patients with high BMI include the deleterious effect on quality scores, the increase in risks to the patient, and concerns about costs. The following justification for this approach seems to be consequentialist in nature: more patients can be treated because of fewer complications, lower costs, and shorter surgical times. These factors result in more patients undergoing total joint replacement with an overall increase in positive outcomes. More patients receive care when surgeons operate only on healthy, low-cost patients.

This reasoning is sound only if consequence is defined by maximizing the number of patients who receive care. However, this is not how healthcare works; indeed, healthcare exists to support the needs of those who are sick, appreciating that they require more care than those who are healthy. Other consequences should be considered. Maximizing the overall good from surgery would entail including patients with the greatest disease burden who would potentially benefit the most. There is an association between obesity and demand for total hip and knee replacement.[35] The Canadian Joint Replacement Registry showed a greater need for total knee replacement among obese patients compared with normal-weight patients: need is 8.5 times higher in patients with BMI of 30 to 34.9, it is 19 times higher in patients with a BMI of 35 to 39.9, and it is 33 times higher in patients with BMI greater than 40.[36] Obese patients are, on average, a decade younger than normal-weight patients when they seek hip and knee replacement surgery, which potentially yields more years of improved quality of life after surgery.[37]

The foundation of refusal of surgery to obese patients has also been grounded in the language of nonmaleficence because of the increased surgical risks for obese patients. Nonmaleficence can be framed in two ways. First, it can be understood as the premise that physicians should never harm a patient intentionally. However, surgeons routinely risk harm for the sake of benefit, so this framing is not a practicable argument. Second, nonmaleficence can be considered part of the consequentialist calculus, whereby one should promote good and avoid evil. Using this definition, the argument to limit surgery to non-obese patients is as follows: although joint replacement is a high-value proposition, the risks are so substantial that including obese patients is, on balance, more harmful than beneficial. I find this argument unpersuasive. There is no evidence that the increased risks of surgery are substantial enough to outweigh the tremendous potential benefits. In fact, there is mounting evidence to the contrary. Obese patients who undergo knee replacement have greater functional improvement than non-obese patients.[38] I am not arguing that all patients who desire elective joint replacement should undergo surgery, ignoring the risks. Rather, I think there is evidence that many patients with a BMI greater than 40 may receive greater benefit than harm from total joint replacement, and the argument of nonmaleficence should be made on a case-by-case basis.

The argument about a patient's best interests is even less persuasive when considering an individual patient as opposed to the general population. We would normally advocate that it is for the patient to determine (using information that the physician provides) whether the risks of surgery are worth the benefits. Respect for patients' autonomy would conventionally be the overriding ethical principle. Patients, regardless of their BMI, should ultimately decide whether to proceed with surgery in the context of shared decision making with their surgeons, provided they are appropriate candidates and understand the risks. An additional concern related to using BMI to determine eligibility is that such screening may occur before an office visit, by the scheduler or other administrative personnel, and obese patients may be redirected to non-operative careproviders or denied a visit altogether. In this situation, patients' autonomy is diminished further by a failure to have surgery as a considered option.

Other incentives for refusing surgery to patients must be part of this discussion. These incentives include increased reimbursement, decreased complications, and less work caring for non-obese patients compared with obese patients. Consideration of these motivations leads to the uncomfortable intuition that refusing surgery is unethical because rejecting surgery for a patient aligns too closely with self-interest. In using self-interest as a justification for denial of treatment, surgeons fail to uphold their fiduciary responsibility to their patients.

Unconscious biases about obese patients may adversely affect clinical decision making.[39] There is a stigma attached to obesity because many consider it, unlike other health conditions, modifiable.[40] The belief that a patient's BMI is mostly under his or her control is inaccurate.[41] It can be quite difficult for patients to lose weight,[42] and it may be unreasonable to require weight loss as a condition for surgery. Additionally, weight loss through bariatric surgery does not appear to decrease complication rates for hip and knee replacement.[43] Misconceptions re-

garding the ability of patients to lower their BMI are another reason to reconsider refusals for joint replacement.

Although consequentialist- and justice-based arguments would support access to these valuable interventions for obese patients, there are additional good, moral reasons to be concerned with BMI cutoffs. Obesity is associated with racial and economic disparities.[44] Refusing to operate on obese patients will disproportionately affect poor and minority populations, further exacerbating justice-based concerns. Minority patients are already less likely to receive total joint replacement, as documented extensively in the literature.[45] White patients are almost twice as likely as Black patients to undergo knee replacement, and this disparity continues to grow.[46] Using BMI as a screening tool will worsen the already marked differences in access to total joint replacement.

LOOKING FOR SOLUTIONS

Using BMI as a screening tool for total joint replacement eligibility raises multiple ethical issues. There is the potential to exacerbate population-based inequalities and to deny high-quality treatment to those in pain. Incentives encourage hospitals and physicians to act in their economic self-interests rather than in patients' best interests.

Although a comprehensive analysis of policy options is beyond the scope of this article, I recommend greater stratification of patients according to risk factors in the payment algorithm. The extensive research on joint replacement outcomes can be used to inform this risk stratification and to determine appropriate compensation on the basis of the higher anticipated costs of caring for obese patients. Although there could be bureaucratic debates in determining how nuanced the risk stratification should be, additional strata could be identified and would likely decrease the accessibility problem for obese patients.

One option for stratification is to calculate the risk of infection or death related to total joint replacement using the American Joint Replacement Registry Risk Calculator.[47] Although this article has focused on obese patients, there are many other subtypes of patients who may be denied surgery because of risks. For example, a patient with end-stage renal disease on dialysis has a much higher risk of infection than a morbidly obese patient.[48] Tiered payments based on risk stratification could remove the financial disincentive for treating higher risk patients, provided the compensation matches the risk. A concern with such a system is that the nuances and complexities of different conditions would be reduced to a percentage and would not capture the complexities of patient care. Rigorous programmatic design could address these concerns.

The former administrator of CMS, Donald Berwick, was famously critiqued for his statement, "The decision is not whether or not we will ration care, the decision is whether we will ration with our eyes open."[49]

The bundling of healthcare services presents an issue for those who wish to ration with their eyes open. As currently structured, the bundled payment system is likely to exacerbate healthcare disparities as physicians perform more joint replacements on the lowest risk patients and limit the provision of these treatments to higher risk patients. Risk stratification or new incentives within bundled payments would better support the goal of rationing with our eyes open.

CONFLICTS OF INTEREST

The author has no conflicts of interest to report. No funding was received in support of this work.

NOTES

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tive MRIs when such conflicts of interest exist seems to suggest that financial incentives to prescribe, consciously or not, tend to lead to overprescribing, and this is not an isolated example. R. Pear, "Doctors who profit from radiation prescribe it more often, study finds," 2013, *http: // www.nytimes.com/2013/08/19/us/doctors-who-profit-from-radiation-prescribe-it-more-often-study-finds.html.*

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Law

Colorado's New Proxy Law Allowing Physicians to Serve as Proxies: Moving from Statute to Guidelines

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ABSTRACT

In 2016, the Colorado legislature passed an amendment to Colorado's medical proxy law that established a process for the appointment of a physician to act as proxy decision maker of last resort for an unrepresented patient (Colorado HB 16-1101: Medical Decisions For Unrepresented Patients). The legislative process brought together a diverse set of stakeholders, not all of whom supported the legislation. Following passage of the statutory amendment, the Colorado Collaborative for Unrepresented Patients (CCUP), a group of advocates responsible for initiating the legislative process, coordinated a unique effort to engage these stakeholders in the creation of a set of voluntary guidelines to assist facilities and individual careproviders in the implementation of policies and procedures enabled by the statute. This article delineates the questions and concerns of stakeholders, describes how those issues were addressed within the guidelines, and proposes additional opportunities for research to assess the impact of the legislation in Colorado.

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INTRODUCTION

Decision making for unrepresented patients is an increasingly common dilemma in healthcare settings, with these patients at risk for under treatment, over treatment, and delayed testing and treatment.[1] Despite much exploration of the topic for the past 25 years, a 2016 position statement by the American Geriatrics Society points to a continued lack of consensus on both legal and clinical practice standards for making medical decisions on behalf of this vulnerable population.[2] The result is a patchwork of approaches across the United States, which may or may not be supported by the diverse range of state laws and very limited research that confirms the numbers of unrepresented patients and investigates the timeliness and procedural fairness of those approaches in practice.

In 2016, the Colorado Collaborative for Unrepresented Patients (CCUP), consisting of healthcare professionals, attorneys, and ethicists, worked together to successfully amend the proxy law in Colorado to include a mechanism to make more timely healthcare decisions for patients who are unrepresented.[3] Amending legislation wasn't the first choice of the members of CCUP, who originally worked to include medical decision making in a public guardianship pilot program that was proposed, but not funded, in 2014. Still committed to better address-

ing the needs and care of unrepresented patients, the members of CCUP turned to the expansion of Colorado's otherwise good proxy statute to include a provision that was specific to unrepresented patients, which allows for the appointment of a physician as the proxy of last resort.

Throughout the process of passing legislation to amend the proxy statute to include physicians as proxies, CCUP leaders navigated a variety of legal, ethical, practical, and political dimensions, some of which were directly addressed in the body of the statute.[4] However, it was not strategic to address every detail in the statute, so the CCUP leadership promised to coordinate the development of a set of guidelines to help stakeholders with the practical logistics of implementing the statute in their facility. They initiated additional communications with stakeholders and convened a large meeting of stakeholders in order to create a set of community-generated guidelines for implementation. This unique approach to the practical implementation of enabling legislation should be of interest to other states considering similar solutions to the dilemma of unrepresented patients.

The final elements of Colorado HB 16-1101, Concerning Medical Decisions for Unrepresented Patients (hereafter, HB 16-1101), reflected the option of a volunteer physician-proxy of last resort with safeguards to protect the very vulnerable population of unrepresented patients. The key provisions of the amendment are listed in table 1. The full bill can be located at the state website.[5]

STAKEHOLDERS' INPUT

The original CCUP was composed of colleagues from multiple disciplines and healthcare settings who then reached out to colleagues in both rural and metropolitan settings in order to obtain the most feedback on issues from the widest array of different perspectives. What to do about medical decision making for unrepresented patients was an ongoing topic at the annual meeting of the Colorado Healthcare Ethics Forum, and its members were a valuable source of feedback. As the legislative process progressed, an extensive list of stakeholders was created. Active stakeholders included representatives of the Colorado Hospital Association, large hospital systems, the major liability carrier, the Colorado Medical Society, the Colorado Nurse Association, the Colorado Bar Association, the long-term care community, and the disabilities community. Following passage of the legislation in the spring of 2016, this list was used in late summer of 2016 to re-engage the stakeholder community in the development of the promised guidelines to address the appointment, termination, and scope of physician-proxies, the role of ethics committees, and other aspects of protecting unrepresented patients.

DEVELOPMENT OF THE GUIDELINES

Throughout the initial process of gathering stakeholders' input and support, CCUP leaders kept the legislative amendment deliberately vague to try to garner maximum support from a wide array of institutions and to try to insure that willing institutions could fashion policies and procedures that best fit their individual contexts when using a physician as a proxy decision maker. Based on feedback from stakeholders before and during the legislative process, the leaders of CCUP were already aware of many of the ethical, legal, and practical concerns that would remain once the legislation passed, that might hinder facilities and individual careproviders from making use of the new law. In fact, the FAQ (frequently asked question) document that was developed during the legislative process served as the starting point for the guidelines, intended to help institutions that were willing to adopt the processes that were outlined in the legislation.

It should be noted that the concept of community-generated guidelines was preferred to regula-

TABLE 1. Highlights of Colorado HB 16-1101, Concerning Medical Decisions for Unrepresented Patients

- Appointment of a physician as proxy decision maker of last resort for an unrepresented patient
- Proxy as physician is separate from patient's attending physician, and assignment is voluntary
- Ethics committee involvement is required for choice of physician as proxy and consensus with treatment decisions that need written consent and for end-of-life decisions
- Independent decisional capacity determination by second careprovider
- Documentation requirements in medical record
- Physician as proxy to be involved in all decisions that would normally require informed consent
- Special end-of-life provisions involve an attending and a second consultant physician, a physician-proxy, and the ethics committee of the institution
- Protection from liability for physician acting as proxy
- Processes for when the role of physician as proxy ends
- Applicable in all healthcare facilities, including hospitals, nursing homes, and hospices

tions, since guidelines are voluntary and can be generated via the community itself, while they can also be easily amended with subsequent experience. Unlike the case with Colorado's statute regarding cardiopulmonary resuscitation—which specifically directed the Colorado State Department of Public Health and Environment (CDPHE) to promulgate regulations—the amended proxy statute that allows a physician to serve as a proxy is voluntary, and the DPHE has never tried to implement a regulation regarding any part of the proxy process. Therefore, neither state statute nor regulation provide specific details on how to implement the basic process outlined in the statute. However, in creating community-generated guidelines, careful language was required in discussions with stakeholders so as not to commit to too much by referring to them as "standards of care" or "best practices." There was a thin line between wanting to capture and encourage practices that would enhance the care of unrepresented patients and setting a required standard that was beyond the scope of CCUP's efforts, could not be applied in some settings, and made legal colleagues nervous.

In the absence of specific regulations, and even though the guidelines are voluntary, their development was essential. Most importantly, the guidelines helped address specific concerns about the use of physicians as proxies that might well have prevented some careproviders and facilities from using the legislation. In addition, the development of community-generated guidelines presented an opportunity to improve practice for unrepresented patients and make it more predictable and consistent across the state. A final benefit of the guidelines was simply the opportunity to educate both individual careproviders and facilities regarding the larger proxy statute itself.

Ultimately, the goal of the legislation was to improve the timeliness, consistency, and fairness of decision making for unrepresented patients as a matter of justice. Passing the legislation was a step in that direction, but not enough, in and of itself, to promote its effective use in practice. Therefore, using the FAQ document as a starting point, an initial set of guidelines for the use of physicians as proxies was drafted and distributed to a small group of volunteer reviewers. Based on their support for the document, the draft was then distributed to the full set of stakeholders who had expressed interest during the legislative process, and a meeting was convened in September of 2016. Based on the extensive feedback gathered during and after this meeting, a guidelines document was finalized and widely distributed later in 2016. CCUP leaders continue to be contacted with questions and requests for education regarding the legislation or assistance with policy development.

THE CONTENT OF THE GUIDELINES

The document, "Decision Making for Unrepresented Patients Who Lack Capacity: Guidelines for Health Care Facilities in Colorado" (hereafter, the Guidelines), which was widely distributed, begins with a preamble to give some context and a summary of the amended proxy law that allows physicians to serve as proxies.[6] It then expands on the intentionally general provisions of the law to provide more detailed descriptions of options and recommendations to operationalize the law in some of the widely differing healthcare sites around Colorado. An outline of the multiple components of HB 16-1101 covered in the Guidelines is provided in table 2; the key issues within each of the topics are discussed below.

1. Identification of an Unrepresented Patient

Assessment of Decisional Capacity. Significant variability exists in how institutions determine if a patient has or lacks decision-making capacity. Criteria have been proposed in prior literature.[7] Some of the CCUP members had been involved in developing policies and processes at their own institution. But such criteria are not widely understood or used. An appendix to the Guidelines was added to demonstrate one version of a tool for documenting the elements of decision-making capacity.

"Reasonable Effort" to Find a Healthcare Proxy. There is considerable confusion about and variability in determining the amount of "due diligence" that is required to determine whether a given person is indeed unrepresented. This determination remains one of the least uniform processes at healthcare institutions. In response, a list of suggested sources of potential family, close friends, or others was added to the Guidelines. The appendices include a tool for suggesting and documenting sites that might need to be researched by a facility prior to considering using a physician-proxy. The scope of due diligence clearly depends on the time and urgency of the decisions that need to be made to care properly for a patient. In the first hours and days of an acute turn that requires interventions needing informed consent, the search is necessarily less comprehensive. For patients who have longer stays, institutions need to continue to search for less obvious sources of information. This persistence in

attempting to locate "interested persons"—as the Colorado proxy statutes describes—is difficult for institutional staff to sustain, but is important to the integrity of the process that allows for a physician to serve as proxy only after no other proxies are found. In addition, documentation of due diligence is often needed when presenting a request for guardianship before a judge.

2. Ethics Committee Roles and Responsibilities

As stated in HB 16-1101, an institution's ethics committee is required to be notified when a potentially unrepresented patient is identified and the use of a physician to serve as a proxy might be necessary. Ethics committees have clear consultative responsibilities that are outlined in the law, and the Guidelines again outline procedures for oversight, review, and documentation, some of which depend on the nature of individual cases. The Guidelines remind institutions that ethics committees should not serve in the proxy role, although ethics committees have additional policy and education responsibilities around the use of a physician-proxy, in keeping with the three common roles for ethics committees articulated in the literature.[8]

Since 1992, the Joint Commission for Accreditation of Healthcare Organizations (JCAHO—now known as the Joint Commission) has mandated that healthcare institutions have a "mechanism for considering ethical issues."[9] While the existence of ethics committees has surged since the JCAHO mandate, a small minority of healthcare institutions in Colorado and elsewhere are not accredited, may lack an ethics committee, and may not be not linked to a system with ethics consultation resources. In addition, there are disparities in the functionality of eth-

TABLE 2. Issues addressed in the Guidelines

Elements of the Guidelines	Topics addressed	Particularly difficult issues
1. Identification of unrepresented patient	• Assessment of decisional capacity • "Reasonable effort" to find a healthcare proxy	• Lack of common legal standard and wide variation in practice
2. Ethics committee roles and responsibilities	• Roles, responsibilities, and problem solving if no ethics committee	• No committee or available alternative • Minimally active committee • Limited committee resources/funding • Lack of committee training
3. Appointment and the role and responsibilities of a physician who assumes the proxy role	• Process of appointment • Role and responsibilities of the physician who agrees to serve as proxy	• Perceived conflict of interest • Willing and available physicians
4. Requirements when using a physician as proxy	--	• Coordination and authority
5. Decision-making standards and conflict resolution	• Types of decisions • Decision-making standards in hierarchical order • Conflict resolution	• Legal concerns • Resolving conflict
6. Guardianship	-- • Process for requesting a guardian	• Might not use when appropriate
7. No willing proxy, termination of physician who is the proxy, and transitions of care	• No willing proxy • Physician who is the proxy resigns • Patient recovers decisional capacity or a suitable proxy is located • Patient discharge or transition of care	• Coordination • Continuity of care
8. Appendices	• Glossary of Terms • Summary of Bill • Decision Making Capacity (DMC) Assessment Tool (and Pearls) • Checklist for Reasonable Efforts to Find a Proxy • Resources for Ethics Consultation • FAQs for Physicians Serving as Proxy Decision Makers for Patients without any Surrogate	

ics committees varies widely across Colorado and the U.S.

Approaches to making decisions for patients without surrogates vary widely across Colorado and across the U.S.[10] In Colorado, the Medical Treatment Decisions Act was amended in 2010 to provide that "the assistance of a healthcare facility's medical ethics committee shall be provided" when a proxy or potential proxy is considering withdrawing or withholding medical treatment. It also states that, if there is no medical ethics committee at the healthcare facility, an outside referral may be used for consultation or assistance.[11]

The requirement for an ethics role is met in different ways by healthcare institutions. Recognizing this, the Guidelines suggest several different ways in which an ethics committee's response can occur, including: oversight by the entire institutional ethics committee with identification of a lead consultant, delegation of ethics responsibilities to a more nimble representative subgroup of persons who are experienced in ethics consultation, the use of system resources for small rural institutions that are part of a larger system, the use of another nearby healthcare facility's resources, or consultation with one of the key ethics organizations in the state. Our disabilities communities strongly encouraged that a patient advocate, ideally with experience with disabled persons, be at the table.

3. Appointment and the Role and Responsibilities of a Physician Who Assumes the Proxy Role

Process of Appointment. The process of appointment of a physician who agrees to be a proxy is clearly outlined in HB 16-1101. In particular, the attending physician can appoint another physician as a proxy, in collaboration with an ethics committee; however, the attending physician cannot directly serve as a proxy. This restriction raised concerns for many institutions regarding how to locate a willing physician to serve as a proxy who would not also be likely to attend as the patient's physician during the patient's healthcare stay. The use of a colleague who is, for instance, a part of the hospitalist or geriatrics group could present a potential conflict of interest. Avoiding the appearance of a conflict of interest is particularly problematic in small institutions, where only one group of physicians may serve. An ethics committee is required to approve the proposed "willing physician," and, in several locations, it has become clear subsequently that a "stable" of potential physician-proxies might benefit from inclusion of physician-administrators or retired physicians at the discretion of the institution or system. In addition, the Guidelines discourage the use of resident physicians and fellows due to the potential lack of independence.

Role and Responsibilities of the Physician Who Agrees to Serve as a Proxy. It has been difficult for potential physician-proxies to understand that their role is one of an advocate speaking on behalf of a patient, not that of a consultant and not as part of the medical team. Education from an ethics committee is required to be sure that this role is clear. For instance, a physician-proxy only has access to a patient's medical chart through institutional policies, in the same way that any other proxy does. Clearly, a physician's medical knowledge facilitates an understanding of the nature of the treatment decisions that need to be made, but this should be no greater than that of any other proxy who also has a medical background. The Guidelines contain an appendix to help give guidance to potential physician-proxies.

4. Requirements When Using a Physician as Proxy

The guidelines indicate the types of decisions in which a physician-proxy will need to participate. In general these include interventions for which informed consent would be required, according to an institution's normal policies and procedures. Special procedures are required under the legislation when end-of-life decisions need to be considered, as with potentially nonbeneficial treatments and withholding or withdrawing life-sustaining treatments. For these decisions, a concurring assessment from a second consulting physician is required, as well as consensus by the ethics committee and consent from the physician-proxy representing the patient.

5. Decision Standards and Conflict Resolution

Types of Decisions. Several institutions asked what kind of treatment decisions would require utilization of a physician-proxy. The interventions can be roughly divided into three levels. (1) Routine treatments that are within broadly accepted standards of medical practice that present a low level of risk to a patient do not require informed consent. Such decisions can be made by an attending physician without proxy consent. This includes such care as blood draws, routine x-ray imaging, and initiating antibiotics. (2) Interventions that normally require a patient's or surrogate's consent would require review and consent by a physician-proxy. Such interventions would include surgery, major procedures

that carry some risk to a patient, such as initiating chemotherapy, placement of a pacemaker, *et cetera,* or treatments for which personal, social, or religious values are expected to differ.

(3) A third and distinct level of consent and consideration is end-of-life management. The legislators involved in HB 16-1101 made it clear that they felt these decisions required special oversight and confirmation. Those stipulations are discussed above. In addition to the three levels of treatment decisions, physicians serving as proxies would be expected to participate in transition and transfer decisions. The controversial issue of organ donation was resolved by consent only in the face of a patient's known wishes (driver's license or other documentation), since there was concern by some legislators that this was the ulterior motivation for this amendment to the proxy law.

Decision-Making Standards in Hierarchical Order. The Guidelines reference accepted standards for surrogate decision making, according to the following hierarchy: a patient's known wishes, substituted judgment, the best interests of the patient.[12] The Guidelines suggest that several factors should be taken into account when a physician who is serving as a proxy considers making decisions using the best interest standard. Institutions are reminded of the vulnerability of unrepresented patients and the need to focus on respect for these patient and their ability to cooperate with any proposed treatments.

Conflict Resolution. The Guidelines encourage mediation internally or through outside referral in the event of an inability to reach consensus among ethics committee representatives, or between a physician-proxy and ethics committee members.

6. Guardianship

The 2016 amendment to Colorado Revised Statutes Title 15, Article 18.5, "Proxy Decision-Makers for Medical Treatment and Surrogate Decision-Makers for Health Care Benefit Decisions," that allows for a physician to serve as a proxy of last resort, is not the ideal resolution to the problem of unrepresented patients. The authors consider this amendment a bridge solution to the need for a robust guardianship program that would allow a dedicated decision maker across institutions and through a life span of medical treatments, if needed. Therefore, a section reminding institutions and ethics committees of definitions and the process of requesting a guardian in Colorado was included in the Guidelines. Appointment of a guardian terminates the responsibilities of a physician who is serving as a proxy.

7. No Willing Proxy, Termination of the Physician Who Is the Proxy, and Transitions of Care

No Willing Proxy. Since a physician serving as a proxy is a volunteer, there will be times when no accepting and acceptable physician-proxy can be found. In such a case, the patient is in the same limbo as he or she would be without this new amendment. Options include appointment of a guardian *ad litem* to assess the situation and perhaps expedite the appointment of a guardian, or to seek a volunteer guardian from the community.

Physician Who Is the Proxy Resigns. A physician serving in the proxy role is a volunteer. The physician-proxy can step aside at any point if the physician feels unable or unwilling to fulfill the role. The Guidelines reiterate the conditions and recommend a process when an appointed physician is unable or declines to continue, to replace a physician serving in the proxy role, or when a patient transitions back to being unrepresented.

Patient Recovers Decisional Capacity or a Suitable Proxy Is Located. Both of these circumstances normally relieve a physician who is the proxy of his/her appointment. When it appears that a patient may have regained enough decisional capacity to resume medical decision making, the ethics committee and attending physician should conduct and document another functional assessment of capacity. A suitable proxy may still need or wish support from the ethics committee. A patient who regains capacity should be encouraged to appoint a decision maker for future times when capacity is lost, and a clarification of values and wishes to inform future decision makers should be carefully documented.

Patient Discharge or Transition of Care. Since one of the most difficult types of decision making involves patient placement, it is very helpful if nursing homes, hospices, and other non-acute-care settings utilize the physician-as-proxy amendment, as these facilities face similar challenges. Access to ethics committee support may be more difficult, and physicians who serve as proxies in one setting often will want to step aside when a patient moves to another setting. The Guidelines reinforce the concept that a new search for a proxy or a physician to serve as a proxy is usually needed at each site of care.

WILL IT WORK? FUTURE RESEARCH AND RESEARCH CHALLENGES

The stakeholder process used to develop the community-generated Guidelines for the implemen-

tation of legislation allowing physicians to serve as proxy decision makers was a unique approach to informing and educating the community, retaining stakeholders' support for the process, and attempting to standardize practice for the benefit of both patients and care teams. The process of drafting the Guidelines was greatly enhanced by reconvening stakeholders, some of whom had actually opposed the legislation for much of the legislative process, but were now ready and willing to assist with its implementation.

However, the passage of the legislation and the community-generated Guidelines constitute only the beginning of a journey to effectively address the specific needs of unrepresented patients and the larger, more general issue of the lack of available guardianship options for this vulnerable population. There is an obvious need for follow-up research to assess the effectiveness of both the legislation and the Guidelines in order to determine what additional steps or resources are needed for successful implementation of the legislation statewide, and the ongoing standardization of the unrepresented patient experience. Among the questions that should be investigated, the following would be good places to start:

- How many facilities, and of what type, have policies and processes in place that allow a physician to serve as a proxy?
- Of the facilities that have policies, how many are actively using those policies?
- Of the facilities that do not have policies, why have they chosen not to implement the legislative option? What are the specific concerns or barriers?
- What alternative process are these facilities using with this patient population?

Once the general use of the physician-as-proxy amendment has been determined, the next area of investigation should be the issues of effectiveness and appropriateness, which raise another more complex set of questions:

- How should effectiveness and appropriateness be defined?
- Should measures of effectiveness be different in different settings?

There are many potential measures that could be considered. Basic descriptive measures could include the number of unrepresented patients identified, the number of patients who needed a proxy and couldn't get one, the number of patients who were assigned a physician to serve as a proxy, the number of physicians willing to volunteer as proxies, earlier and more consistent involvement of ethics committees with unrepresented patients, and the estimated cost savings of receiving more timely and appropriate care and placement via shorter stays or lower overall facility charges. Somewhat more qualitative measures of effectiveness might include reductions in avoidable patient harm and moral distress among care team members. Measures of appropriateness should address the intent of the legislation that allows physicians to serve as proxies and the integrity of the process. For example, are facility ethics committees providing appropriate levels of coordination and consensus?

Finally, and secondary to effectiveness of the legislation itself, the usefulness of the Guidelines should be evaluated:

- To what extent were the Guidelines helpful in developing the policies and processes for using physicians as proxies of last resort?
- How closely do existing policies and processes align with the Guidelines?
- How can the Guidelines be expanded, clarified, or adapted to better reflect community practice and to assist facilities in using the legislation?

To illustrate the potential for research presented by the Guidelines, it is helpful to consider what little we currently know about the initial implementation of the legislation allowing for physicians to serve as proxies. As the Guidelines were being developed, the most engaged stakeholders were hospitals, and specifically the large hospital systems in the Denver Metro area; at least one of these systems extended across the entire state. These systems began developing and implementing policies during the fall of 2016 following the bill's effective date. A year into the legislation, anecdotal evidence is that the policy is being used in at least some acute inpatient settings with success, although the frequency of its use seems to vary widely. However, no definitive data have been collected at this point to determine how extensively it has been used or the barriers to use that remain.

Even less clear is its application in other healthcare settings. For example, there is no available evidence on whether or not smaller and rural hospitals are actively using the statute. Likewise, a recent meeting with one of the major long-term careproviders suggests that long-term care settings are having a hard time with the practical logistics set out by both the bill and the subsequent community Guidelines. At one level, this difficulty should not be surprising, given the primarily acute-care expe-

rience of the drafters of the Guidelines and the involvement of mostly acute-care providers in the stakeholder process. However, most of the barriers are deeper than simple participation in the Guidelines process, and were anticipated even as the bill itself was being drafted.

The feedback from one of our long-term care-providers illustrates the issues that had been anticipated for the use of physicians as proxies in rural and long-term care settings. First is the general concern regarding the unfunded 24/7 time commitment by both the physician-proxy and the ethics committee for every individual case. The majority of ethics committees in Colorado are unfunded and rely predominantly on the volunteer membership of both facility employees and community members, who often find themselves attending meetings on their day off or who may carry a 24-hour pager without compensation. While this issue is present in nearly all acute-care settings, there are simply more options and available human resources upon which to draw in larger settings. The same dynamic is true for the number of physicians who are willing and available to assume the proxy role.

Other concerns include the facts that many smaller hospitals and long-term care (LTC) facilities don't have an ethics committee, or, if they do, the members of the ethics committee receive minimal training and often lack the expertise and other institutional support needed to fully comply with the statute itself, or with the community Guidelines. Another concern that was anticipated was the question of the continuity of physicians serving as proxies, and the transfer of care when a patient moves from one setting to another.

All of these issues warrant further investigation; however, access to the necessary data is a considerable barrier to conducting research, and there is no mandate to track or assess the use of the amended statute. As was experienced during the legislative process, definitive data on something as simple as the number of unrepresented patients, the "patient days" they represent in acute care, and the total charges they incur are simply not available due to a combination of the difficulty in identifying these patients after the fact and competing priorities in facilities that hesitate to dedicate resources to setting up a tracking system. An informal survey of nearly 100 LTC facilities, which the authors conducted with the Colorado Health Care Association (CHCA) prior to introducing the legislation, yielded widely varying data regarding the number of both unrepresented patients who lack capacity and those residents who are immediately at risk of becoming unrepresented and lacking capacity. Presently, the active engagement of an ethics committee, in every case, may ease some of these barriers to information, at least in the facilities that are using the legislation, via the ethics committees' own internal tracking of their activities.

A final development worth mentioning and celebrating is that the successful passage of this legislation allowing physicians to serve as proxies of last resort emboldened its legislative sponsors to run a bill the following year to establish a limited pilot project to study an office of public guardianship. Unfortunately, the budget process did not allow for an appropriation for the study; rather, the study was approved under the caveat that its five-year funding be based on grants, gifts, and donations. A Public Guardianship Commission has been appointed; it is currently working on strategies to collect the initial funds to launch the study. The unrepresented patient legislation in Colorado was never intended to solve the larger scope of guardianship issues for these patients, and there is still a great deal of support among the stakeholder community that came together to address unrepresented patients for the establishment of a public guardianship program in Colorado. However, research into the prevalence and costs, both human and fiscal, associated with this vulnerable population could well be a critical factor in garnering both donor and eventual legislative support for public guardianship.

While the call by the American Geriatrics Society for model legal standards and standardized, systematized methods of decision making for unrepresented patients is reasonable, it is probably not practical in the short term, given the current wide variation in legal codes and actual practice. However, the development of community-generated guidelines for policy and process development by individual facilities, based on existing state statutes, may provide an intermediate step in obtaining consensus on the most workable approaches. In addition, a concerted effort to generate data on measurable outcomes would greatly enhance the discussion, much of which remains more theoretical than practical or evidence based. Recent publications by Courtright and colleagues and Moye and colleagues are heartening examples of efforts to investigate and assess actual practice.[13]

NOTES

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