The Journal of Clinical Ethics

VOLUME 29, NUMBER 4 **WINTER 2018**

At the Bedside

Features

Cases from the Cleveland Clinic

Perspectives

The Journal of Clinical Ethics

6 West Washington Street, Suite 302, Hagerstown, Maryland 21740 USA
240-420-8850 • fax: 240-718-7100 jce@clinicalethics.com www.clinicalethics.com

The Journal of Clinical Ethics, ISSN 1046-7890, print and electronic versions.

The Journal of Clinical Ethics is a peer-reviewed, refereed journal, indexed in PubMed, Research Alert, and Cumulative Index to Nursing & Allied Health Literature.

Please contact Mary Gesford at 240-420-8850 or jce@clinicalethics.com for assistance with subscriptions.

At the Bedside

Helping Patients to Achieve What They Find Most Meaningful in Life

Edmund G. Howe

ABSTRACT

Patients' and families' greatest need is often to do what for them is most meaningful. This may be, for example, their religion, their family, or their doing good for others. This piece will explore ways in which care providers may help maximize these ends. Paradigms offered will include Jehovah's Witness patients needing kidney transplants, a transgender adolescent wanting his sperm preserved, care providers' deciding whether to disclose that a deceased organ donor had HIV, and care providers seeking to do good for children profoundly impaired and adults who feel shame for just existing.

In this issue of *The Journal of Clinical Ethics* (*JCE*), three articles discuss aspects of life through which patients and their family members—or anyone—may find the most meaning: religion, family, and being able to do good. What gives meaning to our lives is of the most importance to all of us, including patients.[1] Thus, as clinicians, to the degree that we can, we should seek to determine what is most important to patients and assign it priority when we treat them. I will consider these three sources of meaning as examples and as paradigms for other values that patients and family members may find most meaningful, and I will consider how we might prioritize these values, as well.

In "Justice and Respect for Autonomy: Jehovah's Witness and Kidney Transplant," Paul J. Cummins and Federico Nicoli ask whether Jehovah's Witness patients should have equal access to kidney transplants.[2] Their article highlights religion and meaning. The authors state that although they discuss only kidney transplants, their arguments apply also to heart, liver, lung, pancreas, and stem-cell transplants. I would go further, and suggest that their arguments apply to all patients who have religious or cultural beliefs that are meaningful to them. I will suggest a response to an additional core question they raise, taking an altogether different tack than many have in the past.

In the second article that I will discuss, "Familial Discordance Regarding Fertility Preservation for a Transgender Teen: An Ethical Case Study," Gwendolyn P. Quinn, Amani Sampson, and Lisa Campo-Engelstein ask whether an adolescent, Kasey, who identifies as transgender, should be able to have her sperm frozen.[3] (Here, I will use "transgender" in place of "nonconforming gender.") Kasey's father opposes freezing Kasey's sperm, and also opposes her transitioning. This article involves family and meaning. I will discuss how clinicians may best ap-

Edmund G. Howe, MD, JD, is Professor of Psychiatry and Director of Programs in Medical Ethics at the Uniformed Services University of the Health Sciences in Bethesda, Maryland; and Editor in Chief of *The Journal of Clinical Ethics.* The opinions or assertions contained herein are the private views of the authors and are not necessarily those of the AFRRI, USUHS, or the Department of Defense. The funders had no role in study design, data collection, and analysis, decision to publish, or preparation of the manuscript. Conflicts of interest: none.

proach resolving such impasses regarding treatment for minors, doing it in a way that maximally benefits both transgender children, whether young or adult, and their parents. I will also discuss the age at which parents or transgender persons should make different decisions, and how clinicians—and we, as a society—might best respond when transgender persons request to freeze sperm or eggs. I will also discuss two articles published in the last issue of *JCE*. Both address what clinicians should do when they discover that a posthumous kidney donor had HIV. The specific questions the authors pursue are whether we should tell the donor's partner and family.

The third article in this issue of *JCE* that I will discuss is "To Give or Not to Give: The Challenge of Pharmaceutical Coupons," by Mihail Zilbermint and Louise Schiavone.[4] The authors ask whether clinicians should give patients free medication samples. The article involves clinicians who want to do good, and is a springboard for asking a host of additional far-reaching questions. For example: Can what some people find most meaningful in their lives harm others? How far should clinicians go to help patients who are worst-off? How may we most help patients find meaning in their lives?

Overall, I suggest that if we want to prioritize helping patients to find meaning in their lives, we have a ways to go. We may need to ask our patients, early on, "What is most important to you?" and then listen. It might seem that there is not enough time for this, but that assumption may not be accurate. A series of studies report that patients' complete opening statements of their concerns took an average of 38 seconds, and none of the patients took longer than 150 seconds to fully elaborate their concerns.[5]

RELIGION

Cummins and Nicoli state that Jehovah's Witness patients are sometimes denied equal access to kidney transplants because clinicians deem them to be at too much a greater risk because they do not accept blood and blood products.[6] A second concern that Cummins and Nicoli raise goes the opposite way: they note that these patients may refuse blood because they fear that if they accept it, they will be ostracized by their religious community. In regard to these decisions regarding the allocation of donated organs, I will first discuss what clinicians might want to consider as they decide whether or not to treat these patients as they would other patients. In regard to the latter concern, I will propose that clinicians might want to take a different tack.

Should These Patients Have Equal Access?

Cummins and Nicoli state that clinicians who do not give Jehovah's Witness patients' equal access to kidney transplants stems from an overreliance on the ethical principle of utility. They cite Robert Veatch in support of their view. Veatch is an acknowledged expert on ethics and specifically on the ethics of kidney transplant. He said, as these authors quote, that justice should generally be prioritized over utility, and that no allocation should be acceptable if it is driven solely by utility.[7] The United Network for Organ Sharing (UNOS) has shared this view. It gave the principle of equal access greater priority than previously was the case, for example, when it enacted new criteria for allocating kidneys in 2003.[8] It did this to reduce the disparity then present between African American and Caucasian kidney recipients.[9]

UNOS continues to strive to balance competing principles in the best possible way. All adult kidney candidates in the United States now receive an expected survival score based on age, time on dialysis, current diabetes status, and whether the candidate previously has had a solid organ transplant.[10] Even though UNOS uses a somewhat complex point system to determine which patients who need a kidney should be accorded the highest priority, it seeks to make this determination sufficiently transparent so that those who want to understand the point system can. Thus, transparency is an additional ethical criterion that was intentionally built into the scoring system, as it currently exists.[11] The difficulty, which is no doubt irresolvable, is that persons have differing views. Patients who need a kidney acquire points in this system, for example, if they are younger and have previously donated a kidney to another person. How much these considerations—much less other conditions—should weigh relative to each other is controversial.

None of the factors currently being considered work against Jehovah's Witness patients having equal access to kidney transplants. These patients may be turned down, not because of policy, but primarily because surgeons who

would perform the transplant don't want to do it without the option of giving the patients blood if they need it.[12] Surgeons may refuse to do this procedure because they feel that it would require them to act against their consciences. The right to follow one's own conscience has been equated to other ethically problematic medical procedures, such as termination of pregnancy and fertility treatment.[13] The right to follow one's own conscience includes policy makers who privately determine priorities and clinicians who carry out the policies. Many healthcare institutions allow administrators and clinicians to follow their consciences.[14]

These considerations could pertain to clinicians who have a role in determining the priority of organ recipients. The consideration that should come first is that Jehovah's Witness patients' refusal of blood and blood products, and any added risk their refusal could cause, are based on their religious beliefs. Our general respect in the U.S. for all people's religious beliefs is well-acknowledged. It is, in one sense, contradictory to respect Jehovah's Witnesses beliefs such that we allow them to die for their beliefs, but at the same time not respect their beliefs sufficiently to give them equal access to kidney transplants when they will not accept blood or blood products.

I will focus next on the relative moral weight and priority that should be given to the principle of equity, as opposed to the principle of utility. Clinicians often have a preference for utility in making decisions because arguments based on utility may be easier to defend than those based on deontological principles. Arguments based on utility can be quantified; they support decisions that are based on what will mathematically provide the greatest good for the greatest number. Those responsible for making decisions may use reasoning based on utility to protect themselves, should their decisions be challenged. That they do this to protect themselves may be outside their conscious awareness. Thus, we should ask ourselves, when we are making these kinds of decisions, whether we should give greater moral weight to deontological values such as equity, even though they may be more difficult to defend.

Finally, reasonable people may differ regarding the question of who should decide which patients warrant the greatest priority. We might always want to ask whether a decision is the best one, but also who should make the decision. We often do this in ethics, for example, when we determine that parents should decide a child's outcome when the child is so ill that there is no valid way to decide what clinicians should do.

Again, Veatch here may lead us. He repeatedly has asked whether clinicians' medical expertise and experience gives them greater ethical expertise, or more enlightened ethical judgment than others, at least to the degree that some clinicians believe. Rebecca Dresser, JD, repeated this concern at a recent Office for Human Research Protections workshop, by asking who should decide what information research participants should receive when they enter a research protocol. This determination might, she noted, best be made by "ordinary" people, rather than by medical experts.[15]

I recall an instance that gives this concern added anecdotal support. After a research project was completed, researchers asked participants what information they wished they had been given before they agreed to participate in the research. Most reported they wished they had been given information that wasn't provided when they signed up: how painful it was to have blood taken from an artery rather than a vein. In the same way that "ordinary" people might decide that additional information should be included in recruiting packets for research protocols that medical experts would miss, ordinary people might offer differently weighted values regarding providing equal access to kidney transplants for Jehovah's Witness patients. Perhaps ordinary people would be more likely to share Cummins and Nicoli's views. Robert Klitzman, MD, an eminent ethicist, recently suggested that, in allocating points to determine who should receive a kidney, it might be better to progressively decrease the points allocated to potential kidney recipients as they get older, rather than allocating points based on age solely to recipients who are under the age of 18, as is currently the case.[16] Based on Klitzman's suggestion, we could ask: Do the existing hearing and consensus panels that set policy on the allocation of organs capture alternative views that should be on the table?

The core questions may be what limits, if any, should be placed on clinicians' being able to exercise their moral consciences, and who should decide on those limits as conditions, like the success of bloodless surgery, continue to change. When there is inequity, as is in this case,

the importance of our asking these questions increases.

An additional consideration, warranting no small ethical weight, is the possible consequence of excluding Jehovah's Witness patients: if they do not have equal access to kidney transplants, they may die. This serious outcome makes a strong case for increasing the consideration of equity in ranking these patients. Similar serious consequences in other contexts have resulted in distinctive policies and practices; for example, when patients can't afford emergency care, they must still be admitted to emergency rooms. Ignoring the possible consequences in these cases assaults the dignity of the patients as people.

Liver transplant could be used as a paradigm.[17] Even though patients who have liver failure due to excessive drinking may resume excessive drinking after they receive a liver transplant, they are given access to transplants notwithstanding this increased risk to the organ.[18] What kind of difference might this make for those making kidney allocation decisions? Even if the effect of these considerations is slight, the outcome for some Jehovah's Witness patients may be life, rather than death. For example, for those who make allocation decisions, these considerations may shift the burden from having to prove that these patients *should* have equal access, to having to prove that they *shouldn't.* I use the word "burden" as it is used in the law, not as in everyday conversation. I do not mean "a heavy load." In the sense I use it, "burden" may be illustrated most clearly by the assumption in U.S. criminal law that an alleged offender is innocent until proven guilty. The prosecution has the burden of proving guilt. If the prosecution does not prove guilt, and the alleged offender may have committed a capital crime, the offender may live. If the defense has this burden, the offender might die.

Clinicians' Options

We can take steps in advance to assist Jehovah's Witness patients that could be lifesaving. For example, we could identify surgeons ahead of time who are willing to operate on them without blood. Some hospitals already do this.[19] This requires that hospitals poll surgeons who have admitting privileges in advance to discern who, if any, would be willing to operate on Jehovah's Witness patients without using blood. The effort could go further. If there are not enough surgeons at a hospital who are willing to operate under these conditions, the hospital could poll surgeons in the wider community. It could continue its outreach further and further until enough surgeons are found to ensure that the hospital is prepared as adequately as possible—even though a Jehovah's Witness patient may have never previously come for surgery.

Similarly, hospitals could seek in advance to identify persons such as elders in the Jehovah's Witness faith who have special knowledge regarding the most effective clinical use of blood substitutes.[20] In the past, clinicians and hospital authorities may have been reluctant to call in these experts. They may have feared that if they called in experts, the experts would encourage patients to refuse blood. This might happen. But how likely it is that it would determine patients' outcomes is open to question. On the other hand, if the experts have knowledge that clinicians lack, the experts' extensive knowledge might save patients' lives.

Jehovah's Witness patients who are hospitalized may refuse blood not because they want to, but because they fear being socially ostracized by members of their church if they accept blood. Their families may arrange for relatives and friends to be with them in their hospital room 24/7, to try to insure that a staff member can't come in while the patients are alone and try to persuade them to accept blood.

In such situations, staff may respond in two ways. Initially they may wait, hoping that family and friends will leave. If they do leave, staff will go to the patients and do what family and friends feared. The other option is for staff to remove family and friends by force. For instance, they may tell family and friends that they simply must leave, that they have no choice. Staff may say, perhaps in an attempt to soften their demand, that it is hospital policy. The policy may not be formal or written, but it may be an informal policy. Staff may understand that they will do this, based on past experience, if such an impasse comes about. They may explain that they must do this to insure that what patients say is what patients truly want. These interventions have an obvious downside. They may destroy the alliance between families and clinicians. If a patient dies, the family may need the clinician's support more than ever. Yet, while the death may be heart-wrenching, the family's religious faith may sustain them.

What might clinicians do instead? Let us assume, hypothetically, that some patients and families believe that if blood is transfused, this will eliminate any hope patients have for eternal life. Of course some Jehovah's Witness individuals may have different beliefs, which is not unusual when individuals share one basic faith. Based on this assumption, we may choose to ally ourselves with patients' family members. We can invite patients and families to meet with us and talk with them about what they all feel. We could, for example, express our own regret and sadness. We could express our understanding of why the patient and family feel they must make the choice they are making. (Ethically, we should still say that the patient can accept blood, but this would be clear from the conversation.) We might say that we wish the patient was young enough that we could transfuse her or him over her or his objections, because then the patient would have had no control over the decision to receive blood, and so would not be held accountable or ostracized. But saying this may risk losing the support of the patient and family.

A last question to be considered is who should carry on these discussions. Many of us, from just knowing that a patient could lose his or her life (and in our view, lose it needlessly), will find such conversations emotionally wrenching. We may be less able to effectively establish an alliance with the patient and family. Paradoxically, staff members who are least emotionally affected may be best equipped to lead these discussions.[21]

FAMILY

Many people would willingly die for a family member. Such a preference may be expressed, for instance, when pregnant women say that they are willing to undergo a surgery that is needed by their fetus, with no consideration of the danger it may pose to them. Consequently, surgeons may agonize over whether they should proceed with surgery.

In this section on family and meaning, I will discuss the core dilemma considered by Quinn and colleagues in their article about Kasey and her father, who disagree about Kasey's trasitioning and about freezing her sperm.[22] I follow this with other important questions raised by the case, involving the age at which transgender persons transition and about preserving their sperm and eggs.

In a subsection, I will present and discuss whether we should tell a posthumous kidney donor's family that the donor had HIV. This case raises the question of how we can best respect the special meaning that members of a family find in each other.

The Transgender Adolescent

Quinn, Sampson, and Campo-Engelstein's article about Kasey, a transgender adolescent, and her father brings up for discussion the frequency of tragic outcomes for transgender individuals. As many as 40 to 60 percent may attempt suicide at some time in their life.[23] Parents' support of their child may greatly prevent this tragic outcome. Thus I will describe a way that we may try to help parents offer their child maximal support.

The Importance of Parents' Support

Parents' support of their transgender child is likely to be critical to the child, at any age. With this support, the child may fare much better, regardless of the many other stresses faced.[24] Experts in treating transgender persons report that parents can fully give their child their support even when the parents continue to have doubts.[25] This should not be surprising. Clinicians who know this may be much more helpful to these children than they might imagine. That is, the transgender child, whether adolescent or adult, may know substantial uncertainty remains in this field regarding when and whether transgender persons should make the changes that will alter their gender identity. Clinicians in the Netherlands, for example, tend to believe, based on research performed there, that transgender persons may change their views regarding their gender more often than transgender persons in the U.S. say they do.[26] There may be various reasons for this. It may be, for example, that the persons studied in the Netherlands who identify themselves as transgender are a different population, with less strong convictions regarding their gender, than those seen by clinicians specializing in treating these patients in the U.S.

Children in the U.S. may know that their parents could still have doubts, even though their parents support them. As a result, the children may feel all the more certain that their parents, supporting them regardless, love them, and, for

that matter, love them unconditionally. The children may conclude, likewise, that their parents will put their child's needs first. But even parents who fully support their child may not know the many ways in which they can unknowingly give or not give their support. Thus, clinicians should alert parents to resources available to them, so that they can help their child as much as they can.[27]

Given these considerations, how can clinicians who, presumably, do not have adversarial beliefs, help parents like Kasey's father, who opposed his child's transgender identity? There are three steps clinicians should consider. First, we can ask parents why they feel as they do, and try to support them. There always will be some validity to the parents' views, and acknowledging this may connote, quite rightly, that we value their views and concerns. By "some validity," I mean that there will be something of concern that can or ought to be recognized, considered, and discussed openly and compassionately—even feelings of hate.

If, for example, parents say that they feel as they do because they fear their child's changes will be irreversible, we can say that we appreciate this, using the example of a teenager who wants to get a tattoo. "Many parents may fear this for the same reason," we can say. We could commend the parents for being so concerned for, and committed to, their child: "You clearly and greatly love your child." We could go on to say that children are often able to forgive a parent who has abused them, knowing the abuser was sick, but they but may not forgive as easily the parent who remained passive but who could have intervened to prevent the abuse.

We could add the horrendous statistics regarding suicide rates in transgender persons. We could say to parents that if they wish to help their child to the greatest extent possible, they need to support their child, and that they can do this, regardless of what they feel about transitioning. We can explain that each day their child lives as a member of the "wrong gender," it may be a living hell for the child. Further, the negative effect may be cumulative. The longer such daily hell continues, the worse chance the child may later be able to enjoy an emotionally rich and fulfilling quality of life.

In seeking to support parents, we may find our countertransference feelings to be most difficult. We may feel angry at the parents because we side with the child, and, as a result, our tone and nonverbal behavior may refute and even offset what we say. Thus, we must at all cost avoid feeling such anger, or, if we can't, to pass this task on to another person who can. It may help us to feel more compassion for the parents if we continually remind ourselves that they may love their child just as much as parents who support their child, and also that what is best for these children still remains significantly open to controversy.

At What Age Should Changes Be Made?

For the best ages at which gender-related changes should generally be made, there are guidelines. Patients' needs and contexts may vary greatly. Thus, serious clinical questions remain—and always will, I suspect—in regard to what we should best do for persons who want to make gender-related changes.[28] I will discuss, then, just a few of the more critical clinical questions we may confront regarding the best age to transition. The first is the singular importance to a child of any age of being able to "fit in" as seamlessly as possible with peers. Not fitting in, its negative short- and long-range effects, may outweigh most other concerns in regard to what is best for the child.

There may be standards, some of which are legal, regarding the age at which individuals have the requisite capacity to make such decisions. Ideally, children might be accorded capacity requirements that are geared to the different kinds of decisions they may make, for example, taking medicines to prevent changes due to puberty to better fit in, or later taking medicines to bring about gender-appearance changes, so that they can better fit in. The hardest question for parents may be the age at which they allow their child to socially change. At a very young age, children may not yet be able to express themselves well verbally. But they may, some believe, be able to express themselves by such behaviors as the toys they prefer to play with.[29]

On the other hand, some parents so strongly fear that they may, even unwittingly, influence their child to adopt one gender or another that they scrupulously seek to avoid giving any cues that the child could read as a hint. The parents thus raise the child as gender-neutrally as they can. Even so, they may have to decide at some time, in some way, the social gender they believe their child feels he or she is.

Freezing Sperm and Eggs

The third and last ethical issue I discuss in this first section involving family is whether Kasey, in the case presented by Quinn and colleagues, should have her sperm frozen. This would apply to the preservation of eggs as well.[30] First, we should recognize how important preserving sperm and eggs is to some people. They may, for instance, see the sole ultimate meaning in life as being able to pass on their genes to biologically related offspring.

Clinicians who miss this may respond to patients who make such a request in a way that, connotatively at least, is demeaning. Clinicians may do this because they see their own view as based on impeccable logic. That is, they may reason—quite rightly —that parents can be as happy, or possibly even happier, with a child they adopt. And *vice versa*: adopted children may be as happy, if not happier, than they would be with a biologically related parent.[31] Thus, clinicians may say, "But you can adopt."

Patients who have requested assistance in having a biologically related child may find this insensitive. They may see the clinician as not being concerned with what they want. Patients may also see this as clinicians' imposing their own views, and, worse, attempting to make patients feel shame for not wanting to adopt.[32] Clinicians may be more prone to offer their views with transgender persons who are younger, like Kasey in the case Quinn and colleagues present. Younger patients may need their clinicians to be optimally sensitive to their felt needs. They are more vulnerable due to their young age, and because they may anticipate that their clinicians will feel more free to offer their own opinions.

At present there are great uncertainties about the effect of the hormones transgender persons may take on their sperm and eggs. We do know that the effects may be substantial.[33] Consequently, freezing sperm and eggs may be necessary. That transgender people want to give birth to biologically related children presents new challenges. This should be considered because the needs of transgender persons, although less common, should be equally addressed as other persons' needs, and, if possible, should be met. Some transgender men may, for example, want to deliver their child.[34] They may want to be able to breast-feed their infant. In this past year, transgender men have done so. Concerns for the infants still make this practice controversial.[35]

Informing Family Members that a Deceased Kidney Donor Had HIV

Two articles in the fall 2018 issue of *JCE* addressed whether clinicians should tell family members that a deceased kidney donor had HIV. In "Positive HIV Tests from Deceased Organ Donors: Should We Disclose to Next of Kin?" Anne L. Dalle Ave and David M. Shaw highlighted the medical gains that clinicians may provide by sharing this information.[36] In "Posthumous HIV Disclosure and Relational Rupture," Laura K. Guidry-Grimes and D. Micah Hester focused on some of the possibly harmful emotional effects of a disclosure.[37] I will discuss primarily the latter effects, because they illustrate the importance of clinicians attending to what patients find most meaningful, and then making this a priority. The psychological effects that Guidry-Grimes and Hester unearthed are examples of family members' concerns to which clinicians should attend.

The source of the harms for family members of deceased, HIV-positive organ donors, as is often the case for transgender persons, is stigma. Stigma is still associated with people who have HIV. Examples continue to abound. For example, a couple chose to have their embryo frozen. They learned that the container that stored their embryo included an embryo from a parent who had HIV. They strongly objected to their embryo's sharing a container with the other embryo. As a result, the other embryo was placed in a separate container, even though, as one clinician put it, even if HIV was present, the virus cannot fly.[38] I will now consider the specific issues that Guidry-Grimes and Hester most insightfully raised.

Finding Meaning in Remembering

A first concern Guidry-Grimes and Hester raised was whether a donor who had HIV would want family members to know this. Key possibilities include: (1) what may have been most important to the donor was his or her legacy with family members and their memory of him or her; (2) while alive, the donor might have cringed at the thought of family knowing the donor had HIV; (3) the donor might have feared this knowledge would damage the beauty of the family's memories of the donor; (4) family might treasure their memories of the late donor, and their knowledge that the donor had HIV might harm their memories (as irrational as that might seem).

Dalle Ave and Shaw pointed out that disclosing the donor's HIV status, at least to a marital partner, might enable the partner to discern that he or she has HIV and get earlier treatment. This might allow the partner to avoid passing HIV on to another person. Should this possible medical gain outweigh the gain of allowing the deceased donor to preserve her or his legacy, and allow family members to remember the donor as the donor may have wished? This question is readers' to resolve, but these questions should at least be on the table.[39]

Not Having an Opportunity to Ask Why

Guidry-Grimes and Hester raised a second potential harm of informing members of a deceased donor's family that the donor was HIV positive. If the donor was married, and the donor's partner was informed of the donor's HIV status, the partner would not able to ask the donor why. For example, why did the donor "stray" from monogamy (if he or she did)? Guidry-Grimes and Hester seem to presuppose that if a donor's partner could discuss this with the donor, it would help. But would it? The question is germane to this specific example, but is also germane in similar situations, when both partners are alive. The partners who are informed may seek out a mental health provider, or may choose instead to share their distress with a primary careprovider they already know.

There are many possible variations of this kind of situation, and I will provide a few points regarding what clinicians may best do.[40] For example, the conflict need not be sexual. Perhaps one partner has had intimate conversations over the internet with a person he or she has never met. He or she may say, and believe, that this is nothing. We could inform him or her that this absolutely isn't the case; what bothers the other partner must dictate. Perhaps the "wronged" partner responds in new and irrational ways, again and again, such as calling the partner at work every hour to reassure him- or herself that the partner is not with the other person. The offending partner may well "squawk" at this. We may be able to clarify for him or her, that such repeated calling may be necessary, at least initially, for the wronged partner, and the relationship, to heal. The offending partner should accept this. But what can we do if the offending partner has died, as in the case of the HIV-positive organ donor? We may point out that, yes, the donor may have erred. Yet, although the donor may have done this, many such people still deeply love their partner.

The surviving partner may, as Guidry-Grimes and Hester noted, become more troubled, and wonder why the deceased partner didn't share this information. With a sudden, devastating awareness, the surviving partner might wonder whether the deceased partner wholly trusted him or her. The surviving partner may wonder whether the deceased partner saw him or her as untrustworthy, as too judgmental. Perhaps there was nothing to their relationship at all? Perhaps it was wholly empty and a sham?

Should a possible, devastating awareness like this play out, we can point out what the surviving partner may not have fully considered: the deceased partner may have not shared this information because he or she loved the surviving partner too much. The deceased may have loved the surviving partner so much that he or she feared that if he or she shared this, the surviving partner would reject him or her.

This kind of intervention may well be beyond what many of us would feel confident and comfortable doing, based on our limited experience and/or training. We might prefer to refer such cases to another. Alternatively, we might not refer, but, although well-intentioned, respond in a way that is mismanaged or misunderstood. We may do this out of an understandable and praiseworthy desire to do good, but this may end up doing harm. I present this, regardless, to illustrate two critical points. First, it is always possible to benefit patients by alerting them to relevant perspectives that they may be missing. But it is preferable when doing to first ask, "Would you be comfortable with my sharing with you an additional perspective? I might be all wrong, but it's up to you. What would you prefer?"

Making this point could restore the surviving partner. In all cases, we should dare to take such initiatives. We should share with our patients alternative meanings that they may have missed. This is particularly the case when an event such as this has damaged the core source of meaning in the patients' lives.

DOING GOOD

In their article in this issue of *JCE,* Zilbermint and Schiavone ask whether clinicians should give patients free samples of medications. Cli-

nicians may especially want to do this when patients can't afford their medications. We want to do this because we want to do good.[41] Zilbermint and Schiavone point out there can be downsides to such generosity. For example, some authors have describe the plight of parents who were given samples of an expensive baby formula for their young infant, only to learn later that the infant greatly preferred the formula, but the parents couldn't afford to buy it.[42]

On the other hand, we can consider the effect that giving out samples may have on bonding with our patients. This bonding could outweigh all other considerations, because these relationships may be necessary to bring about many other positive outcomes. Such relationships may be lifelines for some patients, that enable them to keep going, rather than choose to die.

Regarding the moral weight we should place on bonding between patients and clinicians, throughout the remainder of this last section I will explore the pros and cons of clinicians doing other kinds of "good." First I will look at an example in which we may do a good we believe in, only to miss what may be a much better way to go. Then I will look at the other extreme, in which we may "do good" in a way that is literally lifesaving.

Placing the Good Above What Is Better

In a particularly heated set of articles published in 2015 in *JCE,* authors wrangled over whether a pediatrician or neonatologist should attend the delivery of a pregnant woman who wanted home delivery attended by a midwife, even though the woman and her husband knew that their infant might experience exceptional difficulties after birth.[43] The authors considered whether the pediatrician should attend the delivery to assist the infant. Or, the authors ask, would the pediatrician benefit the infant more by refusing to go to the parents' home for the delivery, which might force the parents to instead go to the hospital for the delivery?

We could ask decisive, empirical questions, such as how likely it would be that the pediatrician's not going to the parents' home would move the parents to change their minds about home birth. But, when confronted, these parents "dig in" and stay with their plan for a home birth. This is a clinically profound truth: we all have an oppositional part of our mind that, when confronted, tends to dig in.[44] We can keep this in mind when we consider how we may be quite wrong when we believe we are only doing good.

For example, a newborn who is doing quite badly in the hospital, medically speaking, because she needs artificial respiration and tube feeding, which cannot ever be removed. Parents in these kinds of situations may be devastated and engage in unruly behavior. The catastrophe may only increase. The staff may focus on the child's outcome and may see, rightly, that the infant may do well, if loved throughout her lifetime, even though she is never able to breathe or eat on her own. Given the staff's focus, if the parents seem insufficiently loving, don't visit enough, don't hold the child when they could, or, worse, deny their child's needs and want to take her home without the technologies that sustain her life, the staff's intent to do good for the child may be stirred. The staff may instruct the parents, with ever increasing force, that the child has the difficulties that she has, needs what she needs, and the parents better shape up. The staff may even surreptitiously contact the hospital legal team to see what they must do if the parents go further and try to take the child home. The staff may envision, even at this early time, the possibility that they will need (with help) to divert the child to an institution or, preferably, to a foster home, to do this child good. The writing on the wall then may become more obvious. The oppositional brains of the parents may be triggered, and it is more possible that the child will be separated from her parents.

An alternative route that the staff can follow is to be indirect. They can put most of their nonmedical efforts into recognizing the parents' pain and responding to it. Then, if the staff can support the parents adequately, the child may go home with the parents, who still feel supported enough to be able to carry out the needed medical caring at home . As this example illustrates, the staff's desire to do what they find most meaningful may mislead them—in the same way, Zilbermint and Schiavone might contend, that giving out free samples can mislead.

There are other ways to do good that focus on building parents' alliance with their children. A first approach is preventative: we can recognize, early on, that some parents are at higher risk. When this is the case, we can come by to see the parents, not to check on them, but to support them.[45] Rather than come by and ask,

"How are you?" we could say something like, "I can't even come close to imagining how much you may feel devastated."

Perhaps surprisingly, a second approach would be to attend to clinicians' needs. The rationale for this is simple: if to any degree parents are distressed, clinicians also will be distressed. This innovative approach involves what informally might be called "the eyeball test." If clinicians roll their eyes when discussing parents or their interactions with parents, we might infer that they feel stressed. We can then do all that we can to try to reduce their stress, for example by giving them an opportunity to debrief.

Ethicists who do regular consults can assess when families appear to be exceptionally distressed. As they seek to address the families' concerns, ethicists can put equal effort into helping clinicians relieve their stress, as well. The underlying assumption here is that the stress of both parties may be triggering each other. Thus, helping both may better help all.

Ethics consultants who know this can welcome the opportunity to help, in advance. Consultants may routinely come to rounds, and, while rounding, can ask clinicians whether parents are having trouble, and thus prepare the clinicians for possible later consultations. The success of such enhanced interventions, intentionally focused on how clinicians hurt, is ultimately dependent on the relational skills of the ethicists and their bonding with clinicians. Ethicists who have prior bonding with clinicians can empathize with their frustration and reframe for them what may be going on that they may be missing—and point out that these things can be easy to miss.[46] For example, in the case of the infant above, ethicists can note that the way the parents are acting is normal: they are devastated. The parents did not expect to have a future with a child on a respirator and a feeding tube. Ethicists can note that such parents can, with sufficient time and support, come to love their child and their life with them, just as much as any other set of parents would.

A third approach to building alliances is the use of a sharing model, if clinicians and parents are stymied as they try to decide together what to do. One highly innovative approach is to ask what the baby would want. In one way, this makes little sense. What could a baby know about what he or she wants? The clinician who came up with this approach says that while the answers that parents and clinicians imagine together may be instructive, this approach, on the other hand, can also be self-interested. It allows parents and clinicians to reduce the guilt they feel, as it allows them to place some imaginary responsibility for what they decide on the child, as well as on themselves.[47] In discussing this question, regardless, the parents and the clinicians are allied. This may be the essential springboard for the child to later do well.

Patients' Gains from Clinicians Helping Them Find Meaning

Clinicians who treat patients with cancers know how these patients hurt. Most clinicians who enter this field anticipate and willingly accept making extra efforts for their patients. The clinicians know that they themselves will suffer exceptional emotional pain. An example that needs no explanation is sharing bad news. The predictable aspects of this practice were recently documented in a study of 22 medical oncologists.[48] One internist said in regard to the need to be accessible, "It hurts sometimes but you have to be available."[49] Many of those studied said that their interest in working with profound emotions brought them to this specialty.[50] One said that the especially demanding emotions they are likely to feel are crucial to their sense of themselves. These emotions reflect, this clinician said, "the meaningfulness of our work and the role we play."[51] This kind of increased availability is exceptionally beneficial to patients.

Turning back to pediatrics for an example, I recall talking with parents who had a child who could neither talk nor walk, and never would, and who needed around-the-clock care. The parents, as a result, hadn't taken a day's vacation away from the child for more than 10 years, although they had other children with whom they would have loved to go away, "as other children could." The parents began to see a new pediatrician. On learning of their situation, the pediatrician said that she would be happy to find a nurse who would stay with their son, and she would make herself available throughout their time away, 24/7. The parents and the other children then did go to the beach, loved it, and have spoken of this pediatrician, gratefully, ever since.

Clinicians who find it meaningful to be especially available, like this pediatrician, may meet their patients' needs more than is evident. This often is the case in psychiatry. Here patients

may experience sudden, meltdown turmoil. One patient called me at home at 4 a.m. She was falling apart because a past assault had been retriggered. Within a half hour of our talking, she was calm. It continues to amaze me how a person who is wholly disheveled emotionally can rally in response to a trusted other in so little time. As Elvin Semrad, a much renowned psychiatrist at Harvard said, even patients who appeared to be very psychotic became, in their contacts with him, understandable human beings.[52]

I end this section with an extreme example that is meant to illustrate how far clinicians may go in their choice to do what is most meaningful to themselves. The kind of patients considered here are rare, perhaps, although they may exist more commonly than any of us recognize. These are patients whom one psychiatrist described as feeling shame just for existing. The psychiatrist describes one patient using the patient's words: "My presence, my being is a burden on those around me, on humanity, on the world."[53] As this psychiatrist describes it, the shame of existing, as opposed to other forms of intense shame, is not shame felt for an aspect of who or how the patients feel they are, but pertains to their merely existing. Whereas shame is usually characterized by the urge to hide and conceal, the shame of existing impels the subject to wish to disappear or dissolve.[54]

These patients feel empty inside. They may dread the nighttime, when they wake up and then can't return to sleep, only to dread more when they awake in the morning. Every day, every minute, they may wish they were dead. How might they come to be this way? One possibility is as follows. A mother chose not to look at her newborn for days after he was born. She told him when he was older that she wished she had never had him.[55]

How might a psychiatrist who is wholly devoted to such a patient intervene? An example is the psychiatrist Frieda Fromm Reichmann. She, it is said, would return time again and again for sessions with a withdrawn and uncooperative patient who would not talk to her until the patient could bear it no more and would then open up to her.[56] However, as is evident from this example, more than the usual approach may be required. Some psychiatrists who do this work have said that, for these patients, clinicians must radically depart from standard practice.[57] This may involve, for example, abandoning their traditional hierarchical place for one that is equal. For example, in response to a patient's asking, "How old are you?" rather than ask, "Why do you ask?" they may respond, "I'll tell you, if first you tell me why you ask."

CONCLUSION

I have reviewed three core sources of meaning in life: religion, family, and doing good. I have suggested in regard to religion and specifically Jehovah's Witnesses that clinician may ally themselves with patients, even when this means accepting the patients' death. I have suggested that clinicians who meet with parents regarding a transgender child first validate the parents' views, then celebrate who and how they are, and then tell the parents what they must do if they love their child.

I have given examples of how clinicians who prioritize what is the most meaningful to them, such as doing good, may have both bad and good results. They may give priority to their own principles, and not see that forming relationships with patients may be the only way they can achieve what they want. To reach and help patients who are the worst-off, like patients who feel shame for existing, they may have to abandon the usual tenets of their practice.

Our own reason for living, presuming we have one, may be paramount in our life, although it may be out of our awareness, or around the corner. We must never forget the importance of meaning in life when we treat our patients.

An excellent example of such meaning is presented by Arthur Miller in his play *The Crucible*.[58] The lead character, John Proctor, is a loving husband and father who is caught up in the hysteria of 17th century witch trials in colonial Massachusetts. At the end of the play, a court determines that Proctor must either confess to being a witch—which will result in punishment, but not death—or deny he is a witch, for which he will be hanged as a liar, as the court has determined this would be a lie. Proctor's wife tells him he must do what he determines to be right. He writes a confession to save his life, but then tells the truth, and is hanged. For this character, like Jehovah's Witnesses, the price of death for doing what is meaningful is not too high.

NOTES

I would like to thank Norman Quist for his most insightful comments on this article.

1. C.E. Hill et al., "Meaning in Life in Psychotherapy: The Perspective of Experienced Psychotherapists," *Psychotherapy Research* 27, no. 4 (July 2017): 381-396.

2. P.J. Cummins and F. Nicoli, "Justice and Respect for Autonomy: Jehovah's Witnesses and Kidney Transplant," in this issue of *The Journal of Clinical Ethics,* volume 29, number 4 (Winter 2018).

3. G.P. Quinn, A. Sampson, and L. Campo-Engelstein, "Familial Discordance Regarding Fertility Preservation for a Transgender Teen: An Ethical Case Study," in this issue of *The Journal of Clinical Ethics,* volume 29, number 4, (Winter 2018).

4. M. Zilbermint and L. Schiavone, "To Give or Not to Give: The Challenge of Pharmaceutical Coupons," in this issue of *The Journal of Clinical Ethics,* volume 29, number 4, (Winter 2018).

5. R.M. Frankel and H.B. Beckman, "Accuracy of the Medical History: A Review of Current Concepts and Research," chap. 45, in *The Medical Interview*, ed. M. Lipkin, Jr., S.M. Putnam, and A. Lazare (New York:Springer, 1995), 218, 511-24.

6. Cummins and Nicoli, "Justice and Respect for Autonomy," see note 2 above.

7. Veatch has advocated the priority of deontological over consequential values in other contexts. I recall, for example, decades ago, at an annual course on bioethics at the Kennedy Institute of Ethics in Washington, D.C., that an attendee asked him the ethical grounds, if any, on which he thought it might be permissible to override the advance directive of a patient in a persistent vegetative state who had indicated that she wanted to be kept alive. This was when it was presumed that such patients could not at all recover. Veatch's answer was "justice."

8. E.C. Hall et al., "Effect of Eliminating Priority Points for HLA-B Matching on Racial Disparities in Kidney Transplant Rates," *American Journal of Kidney Diseases* 58, no. 5 (November 2011): 813-6.

9. Veatch, when teaching this, would ask learners rhetorically who would get all the kidneys if utility was the only principle used. "All white middle-class males," he would respond, depicting in his voice and expression the wrongness of this outcome.

10. "The New Kidney Allocation System (KAS): Frequently Asked Questions," 4 December 2014, *https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.*

11. P.A. Mayer, D. McElfresh, and G. Schnickel, "'OK Google—Who Should Get this Kidney?' Artificial Intelligence and Transplant Algorithms," presentation at the 20th ASBH 2018 Annual Meeting, 18 October 2018, Anaheim, Calif.

12. Ibid.

13. R. Trzcinski et al., "Surgery in Jehovah's Witnesses—Our Experience," *Przeglad Gastroenterologiczny* 10, no. 1 (2015): 33-40.

14. Ibid.

15. R. Dresser, "Laying the groundwork for meaningful informed consent," presentation at the OHRP Exploratory Workshop: Meeting New Challenges in Informed Consent in Clinical Research, 7 September 2018, in Rockville, Md., *https://www.hhs.gov/ohrp/education-and-outreach/upcoming-educational-events/ohrp-exploratory-workshop-tentative-agenda-09072018/index.html.*

16. Mayer, McElfresh, and Schnickel, "OK Google," see note 11 above.

17. T. Wu et al., "Controversies in Early Liver Transplantation for Severe Alcoholic Hepatitis," *Annals of Hepatology* 17, no. 5 (24 August 2018): 759-68.

18. Ibid.

19. M. Reitar, "Relational Autonomy, Care, and Jehovah's Witnesses in Germany," *Bioethics* 32, no. 3 (2018): 184-92.

20. Ibid. All Jehovah's Witnesses may not have the same views, especially in regard to storing and then using their own blood.

21. There has been much discussion of practice with Jehovah's Witness patients over past decades. See, e.g., J.L. Dixon and M.G. Smalley, "Jehovah's Witnesses: The Surgical/Ethical Challenge," *Journal of the American Medical Association* 246, no. 21 (1981): 2471-2.

22. Quinn, Sampson, and Campo-Engelstein, " Familial Discordance," see note 3 above.

23. A. Antommaria, Z. Goldstein, H. Mabel, and E. Reis, "Looking to the Past, Understanding the Present, and Imagining the Future of Bioethics and Medical Humanities: Engagement with Transgender Health," presentation at the 20th ASBH 2018 Annual Meeting, 19 October 2018, Anaheim, Calif.

24. E. Nealy, *Transgender Children and Youth* (New York: Norton, 2017).

25. C. Ryan, "All in the Family: Changing the Paradigm for Wellness, Prevention and Care for LGBT Children and Youth," presentation at the 143rd Spring 2018 Meeting of the Group for Advancement of Psychiatry, 13 April 2018, White Plains, N.Y.

26. Antommaria, Goldstein, Mabel, and Reis, "Looking to the Past," see note 23 above.

27. Nealy, "Transgender Children and Youth," see note 24 above, p. 345. Free and confidential peer-support hotline numbers for GLBT individuals are 1(888)843-4564, 1(800)246-7743, and 1(877)565-8860.

28. Clinicians may have to strictly adhere to present standards of care, as those of the World Professional Association for Transgender Health, for medical insurance companies to pay for transgender persons' treatment.

29. J. Brooks, "Is Three Too Young for Children to Know They're a Different," *KQED Science*, 26 August 2018. This story links to a radio interview Jack Drescher did in May 2018, *https://www.kqed.org/futureofyou/440851/can-you-really-know-that-a-3-year-old-is-transgender.* Parents such as Kasey's father may ask, "What if she later changes her mind?" We could respond, "The more worrisome question is, what if she doesn't?"

30. E.K. Johnson et al., "Fertility Preservation for Pediatric Patients: Current State and Future Possibilities," *Journal of Urology* 198, no. 1 (July 2017): 186-94. Additional concerns that Quinn, Sampson, and Campo-Engelstein raise are: Who should pay? How? They cite approximate costs. This raises a question of justice, which, in this case, is especially warranted, since bearing biologically related children may be to some people so singularly meaningful. Transgender persons may be harmed by stigma within society. Based on this harm, the public's support for sperm and egg preservation for persons in this group might be considered, based on the principle of compensatory justice. Quinn, Sampson, and Campo-Engelstein, "Familial Discordance," see note 3 above.

31. A possible reason that adopted children and their parents may be happier, howsoever construed, is that these parents wanted these children and jumped hurdles to be able to adopt them.

32. This example exemplifies the risk that clinicians may take on, should they assume that what patients will feel is what seems logical to the clinicians.

33. Antommaria, Goldstein, Mabel, and Reis, "Looking to the Past," see note 23 above.

34. They may prefer having a midwife deliver their baby at home. A transgender man gives this reason: "I knew early on that I really wanted to have a midwife. The idea to me of walking into a hospital, in labor, and trying to explain to every single person I met who I am, was very scary to me." J.C. Valente, "The Midwives Who Help Trans and Non-Binary Parents Give Birth," *Kveller,* 7 July 2017, *https://www.kveller.com/the-midwives-who-help-trans-non-binary-parents-give-birth/.*

35. Even research to determine whether the medicinal means to bring this about are harmful may be ethically impermissible: "Given that there is a safe alternative to feeding infants whose mothers cannot or will not breast-feed, namely, bottle-feeding, how could a clinical trial to determine the safety and nutritional value of breast milk from induced lactation be justified?" B. Steinbock, "Breastfeeding and Transgender Women," *Hastings Bioethics Forum,* 21 February 2018, *https://www.thehastingscenter. org/breastfeeding-transgender-women/.*

36. A.L. Dalle Ave and D.M. Shaw, "Positive HIV Test Results from Deceased Organ Donors: Should We Disclose to Next of Kin?" *The Journal of Clinical Ethics* 29, no. 3 (Fall 2018): 191-6.

37. L.K. Guidry-Grimes and D.M. Hester, "Posthumous HIV Disclosure and Relational Rupture," *The Journal of Clinical Ethics* 29, no. 3 (Fall 2018): 196-201.

38. Ethics Committee of the American Society for Reproductive Medicine, "Human Immunodeficiency Virus (HIV) and Infertility Treatment: A Committee Opinion," *Fertility and Sterility* 104, no. 1 (July 2015): e1-8.

39. We now have better treatments for HIV. This raises the question whether ethically this answer is different today than when HIV first appeared and there were no effective treatments.

40. I offer these comments in response to questions raised by Guidry-Grimes and Hester, to show how we might salvage the meaning that patients and families have for each other, when they are alive and after one has died. Guidry-Grimes and Hester, "Posthumous HIV Disclosure," see note 37 above.

41.The concept of doing good is open to question philosophically and psychologically. Philosophically, it is debated whether all altruism is self-interested. For a recent review of how altruistic behavior may be complex, see A. Tusche et al., "Decoding the Charitable Brain: Empathy, Perspective Taking, and Attention Shifts Differentially Predict Altruistic Giving," *Journal of Neuroscience* 36, no. 17 (27 April 2016): 4719-32. Helping patients achieve what is meaningful to them may be meaningful to clinicians. See in this regard, A.L. Suchman, W.T. Branch, and D.A. Matthews, "The Role of the Medical Interview in the Physician's Search for Meaning," chap. 30, in *The Medical Interview,* ed. M. Lipkin, Jr., S.M. Putman, and A. Lazare (New York: Springer, 1995), 368-75.

42. K.A. Katz, E.E. Reid, and M.M. Chren, "The Good, the Bad, and the Ugly of Free Drug Samples," *JAMA Dermatology* 150, no. 11 (November 2014): 1238.

43. J. Jankowski and P. Burcher, "Home Birth of Infants with Congenital Anomalies: A Case Study and Ethical Analysis of Careproviders' Obligations," *The Journal of Clinical Ethics* 26, no. 1 (Spring 2015): 27-35; M. Cheyney, "Of Missing Voices and the Obstetric Imaginary: Commentary on Jankowski and Burcher," *The Journal of Clinical Ethics* 26, no. 1 (Spring 2016): 36-9; E.G. Howe, "Professionalism: One Size Does Not Fit All," *The Journal of Clinical Ethics* 26, no. 1 (Spring 2016): 3-15.

44. See, e.g., F.A. Chervenak et al., "Neural Mechanisms Underlying Individual Differences in Control-Averse Behavior," *Journal of Neuroscience* 38, no. 22 (2018): 5196-208.

45. C. Collura, J.A. Krick, M. Arnolds, and D.M. Feltman, "Can You Hear Me Now? Amplifying the Voices of Parent Stakeholders," presentation at the 20th ASBH 2018 Annual Meeting, 19 October 2018, Anaheim, Calif. Family members who are at high risk who may trigger a preventive interaction may include parents who fight, parents who lack critical understanding even after multiple briefings, and family members who have difficulty understanding due to speaking a different language.

46. Ibid.

47. Ibid. Parents and clinicians who are aware that they may use this imaginary exercise for their own needs may reduce this possibility. For both parties to ask this imaginary question together may contribute to their bonding, especially over time. See, i.e., M. Rossigna-Milon and E.T. Higgins, "Epistemic Companions: Shared Reality Development in Close Relationships," *Current Opinion in Psychology* 23 (11

January 2018): 66-71.

48. W.T. Wong, A. Broom, E. Kirby, and Z. Lwin, "What Lies Beneath? Experiencing Emotions and Caring in Oncology," *Health,* 24 September 2018, 1-18. (Nine patients in the study were women; 13 were men.)

49. Ibid., 15.

50. Ibid., 12.

51. Ibid., 8.

52. M. Good, "Elvin V. Semrad (1909-1976): Experiencing the Heart and Core of Psychotherapy Training," *American Journal of Psychotherapy* 63, no. 2 (2009): 183-205, 186.

53. R. Wille, "The Shame of Existing: An Extreme Form of Shame," *International Journal of Psychoanalysis* 95, no. 4 (2014): 695-717, 695.

54. Ibid.

55. Ibid., 706.

56. J. Maltsberger, "Treating the Suicidal Patient/ Basic Principles," *Annals of the New York Academy of Scien*ces 92, no. 1 (2001): 158-68, 161.

57. "One of the principal characteristics of the real relationship must be that the therapist will love the patient and not conceal this fact." Maltsberger, ibid.

58. A. Miller, *The Crucible* (New York: Dramatists Play Service, 1953).

Of this play, Miller wrote, "The witch-hunt was a way of saying, 'You must gather to us in the church since we alone stand between you and the Devils overwhelming the world.' Beneath high moral dudgeon, then as now, lay our old friend power, and the lust for it. When several hundred thousand people had been executed in Europe for witchcraft, it was hardly wisdom to say that the cause was merely imaginary." A. Miller, *Timebends: A Life* (New York: Grove Press, 1987).

Features

Familial Discordance Regarding Fertility Preservation for a Transgender Teen: An Ethical Case Study

Gwendolyn P. Quinn, Amani Sampson, and Lisa Campo-Engelstein

ABSTRACT

A 16-year-old adolescent who identifies as transgender wishes to consider fertility preservation prior to the use of gender-affirming hormones. The adolescent's parents are divorced, and one parent supports fertility preservation while the other does not. This case explores the minor's future reproductive autonomy and parental decision making in a field where there is limited evidence of known harms and benefits to the use of fertility preservation in the transgender population and about future potential regret from lack of consideration of fertility preservation during the prime window of opportunity. This case is created from a composite of cases seen at multiple institutions.

Gwendolyn P. Quinn, PhD, is Livia Wan Endowed Chair, Vice-Chair Research, and Professor in the Department of Obstetrics and Gynecology and in the Division of Medical Ethics, Department of Population Health, at New York University School of Medicine in New York, New York. *Gwendolyn. quinn@nyulangone.org*

Amani Sampson, BA, is Senior Research Coordinator in the Department of Obstetrics and Gynecology at New York University School of Medicine. *Amani.sampson@nyulangone. org*

Lisa Campo-Engelstein, PhD, is an Associate Professor at Alden March Bioethics Institute Department of Obstetrics and Gynecology and an Associate Professor at Albany Medical College in Albany, New York. *campoel@amb.edu*

CASE

Kasey is a 16-year-old born with XY chromosomes and male genitalia, who identifies as transgender. Diagnosed with gender dysphoria at age eight, Kasey's preferred pronouns are *they, them,* and *theirs.* Kasey has been socially transitioned since age nine and began taking puberty blockers at age 10. Kasey's father, Keith, is a registered nurse. He and Kate, Kasey's mother, are divorced. Kasey has been under the regular care of a psychologist and pediatric endocrinologist since the age of eight and was advised that decisions for gender-affirming hormones would be discussed at age 16. (Gender-affirming hormones induce characteristics of the desired sex and reduce characteristics of the natal sex.) Kasey is excited about the prospect of hormones and has had many long conversations with Kate about Kasey's desires and future goals to one day be in a committed, romantic relationship and a parent. Kate is in agreement with and supportive of Kasey's choices, but Keith is not. During visits with the physicians involved in Kasey's care, Keith asked to see medical evidence about the side-effects of hormones in teens and young adults and potential adverse effects. Keith was displeased with the lack of evidence available.

In the process of discussing the impact of hormones, Kasey learned her fertility might be

impacted. The family was advised of fertility preservation options that could store Kasey's gametes—sperm—for future use. However, since Kasey has been on puberty blockers from an early age, she would have to cease taking the blockers to see if sperm production would resume. Kasey is very interested in this option, as she has always wanted to be a parent, and although Kasey is not sure of her sexual orientation yet, she currently feels more attracted to people who identify as female. Kasey hopes one day that her stored sperm could be used during in vitro fertilization to create a biological child with a woman she loves. Keith does not support attempts at fertility preservation, believing it to be a waste of the family's limited financial resources. Kasey's physician mentions that there are no known charity or special needs funds available to cover some of the costs, but offers to look into it. Keith thinks the consideration of fertility and preservation is too much to consider with all of the other decisions that have to be made. Should Kasey be permitted to pursue fertility preservation despite Keith's concerns?

DISCUSSION

This case involves a tension between parental decision making and a minor's future reproductive autonomy. Kasey is interested in fertility preservation, believing she will want to be a biological parent in the future, whereas Keith thinks fertility preservation is a waste of limited resources. It is important to note that Keith is not just opposed to fertility preservation, but he is also generally unsupportive of Kasey's gender-affirming treatments. Kate, in contrast, agrees with all of Kasey's treatments, including fertility preservation. This issue of parental discord is also a factor in this case, and generally courts have ruled that the custodial parent has the final say in health matters pertaining to the minor.[1] There are also additional options for mediation, such as allowing a neutral third party to make a decision.

We may question whether Keith's opposition to fertility preservation is due to his broader disagreement with Kasey's gender-affirming treatment. When making medical decisions for their children, parents are supposed to act in the child's best interest. While Keith may have some justifiable concerns about hormone treatment, the harms associated with not undergoing this treatment (for example, psychiatric comorbidities and life-threatening behaviors) may be greater than the harms of the treatment.[2] Youth and adults with persistent gender dysphoria have significant potential for suicide or self-harm if they do not receive the services needed to resolve the dysphoria, and while infertility can greatly impact quality of life, it is not life-threatening.[3] Furthermore, hormone treatment is considered to be standard of care: numerous professional medical societies support gender-affirming treatment for transgender youth, and a growing number of insurance companies cover this treatment.[4] Keith's lack of support for Kasey's gender-affirming treatment will likely adversely affect Kasey's well-being. The healthcare team may want to consider having a one-on-one conversation with Keith about Kasey's treatment overall and also try to tease out whether Keith's views on fertility preservation are part of his general opposition to gender-affirming treatment.

Keith's opposition to fertility preservation may be a barrier to Kasey's receiving it, because, in most states, minors need parental consent for the use of hormones and to have fertility preservation.[5] In contrast, if Kasey were seeking other reproductive services, such as contraception, these could be obtained without parental consent in most cases in most states.[6] This raises the question of why fertility preservation should be treated differently than other reproductive services. While abortion is the exception to these reproductive services, due to its controversial nature, fertility preservation for minors has wide support in the medical and bioethics literature, at least for cancer patients.[7] Presumably the same arguments supporting fertility preservation for minors with cancer would apply to transgender individuals. Yet the same dilemma arises in the oncofertility realm when clinicians discuss fertility preservation for children and their parents oppose it.[8]

One of the main factors that differentiates fertility preservation from other reproductive services is cost. Whereas various reproductive services are typically relatively inexpensive and covered by insurance, fertility preservation can be quite expensive and is generally not covered by insurance. The cost of collecting a semen sample, testing the sample to assess suitability for storage, and the yearly storage fees vary by state, but are estimated to be $500 for initial collection and testing and $300 for yearly storage fees.[9] To date, there are no charity programs of-

fering financial assistance for gamete cryopreservation in the case of a transgender individual. Thus, it is a stark reality that the costs alone may prohibit Kasey's parents from consenting for the procedure. Some individuals have pursued crowd-funding campaigns to cover the cost of fertility preservation, but this has not been widely adopted.[10] Further, some reproductive clinics allow payment plan options that may make such procedures more affordable, but would require the "patient" to be at least 18 years old if the parents are not willing to sponsor the loan.

Without Keith's consent and financial support, it seems unlikely that Kasey will be able to undergo fertility preservation since she probably cannot afford fertility preservation on her own. In our healthcare system, the positive right to particular medical treatments is limited, sometimes based on financial resources. Given that fertility preservation, like much of reproductive medicine, is often seen as "elective," it does not receive the same degree of priority as other treatments, even those treatments that are not lifesaving but dramatically improve the quality of life.[11] Decades of data indicate that infertility can negatively impact psychosocial health.[12] Limited studies have been conducted on the potential regret and impact on quality of life among older transgender adults who did not use fertility preservation and are now infertile.[13] However, we know that some transgender individuals, like Kasey, value biological parenthood.[14] Although some research reports low utilization of fertility preservation by transgender adolescents, another study found that 40 percent of transgender individuals chose to undergo some form of fertility preservation before gender-affirming treatment.[15] Further, among those studies that report low use of fertility preservation, there were high rates of youth saying they intended to adopt children.[16] This suggests transgender youth may have different perceptions of parenthood and family composition than cisgender populations. (*Cisgender* denotes persons whose experiences of their gender correspond with the sex they were assigned at birth.)

While fertility preservation for transgender teens is relatively new, in the oncology realm there is established support for fertility preservation for minors because it will ensure them an open future (that is, the possibility for biological children).[17] Here, fertility preservation would also allow Kasey an open future, thereby enhancing her reproductive autonomy. This is particularly important for Kasey, not only because she has expressed an interest in fertility preservation, but also the goal of being a biological parent. Other avenues for parenthood, such as the use of a gestational surrogate or adoption of an infant, are often challenging for all populations due to high costs and state laws in the United States. While it should not be so, our society often makes it challenging for people who are "different," whether as a cancer survivor, member of a same-sex couple, or transgender individual, to adopt.[18] Unlike in the oncology world, the actual risk of infertility from gender-affirming hormones is less well known, and recent research documents report inconsistent risks and outcomes.[19] As such, it is challenging for a careprovider to give definitive, evidence-based information about Kasey's risk of infertility.

At 16, Kasey is probably mature enough to make her own reproductive decisions. There is consensus in the medical literature that minors should be included in both discussions and decisions regarding their healthcare, appropriate to their understanding and maturity.[20] Furthermore, as treatment decisions become more subjective, minors' involvement should increase.[21] Reproduction is seen as a deeply personal endeavor, one that is best made by individuals themselves rather than by proxy. The private nature of reproductive decision making underpins why minors are legally permitted to make most of their own reproductive decisions. Transgender reproductive decisions do not always reflect a minor's wishes due to parental discord, lack of finances, or decisions made at one developmental age that do not remain true in adulthood.[22] Since Kasey is actively involved in decision making regarding her gender-affirming care, it may seem unfair to minimize her role in or exclude her from decisions regarding fertility preservation.

The next step for Kasey, her parents, and the healthcare team is to have a frank discussion of fertility threats and options with all parties present. Kasey should be allowed to express her values and goals for biological parenthood, and Keith should also be able to state his concerns. The American Academy of Pediatrics (AAP) recommends that careproviders attempt an arbitrative model of handing family discordance, as it offers the potential to maintain "family cohesiveness by respecting the authority of parents

and the developing autonomy of children."[23] Along the lines of the AAP recommendation, a recent commentary suggests a pediatric clinician's primary obligation is to the child.[24] Since Kasey is a minor and needs both financial support and consent from her parents for fertility preservation, it may not be appropriate for a healthcare provider to encourage Kasey to pursue preservation over her parents' objections. However, depending upon the divorce agreement, Kate may have the legal authority to make medical decisions for Kasey without Keith's consent. If Kate and Keith have a divorce agreement that requires shared decision making, Kate could appeal to the justice system to win final decision-making authority for Kasey on behalf of maintaining her health and well-being.[25]

If Keith remains opposed to fertility preservation or if he and Kate conclude that even though they are supportive of it, they cannot afford it, Kasey still has some other options for biological parenthood. First, Kasey could delay her treatment until she reaches the age of 18 and can make such decisions without parental consent. However, as previously mentioned, delay of treatment for gender dysphoria often has devastating consequences for youth, with high rates of suicide and other self-harm injuries as well as substance use and abuse.[26] Second, Kasey could pursue emancipated minor status to pursue fertility preservation, although she would still need the finances for such treatment. Crowdsourced funding and community-based fundraising could allow Kasey to obtain the needed funding. Third, Kasey could go off hormone therapy as an adult in an attempt to create a biological child. Yet, the worry with this course of action is that the effects of cross-sex hormones on Kasey's future fertility remain unknown.[27] Transmen have carried pregnancies by pausing their hormone therapy. (A *transman* is a man who was assigned female gender at birth.) A pause in hormonal therapy to re-initiate sperm production may also be a viable option for transwomen who wish to pursue biological parenthood.[28] (A *transwoman* is a woman who was assigned male gender at birth.) This option should be discussed by the healthcare team if Kasey is unable to access fertility preservation treatment.

CONCLUSION

Healthcare teams who are presented with parental discordance over a transgender adolescent's desire for fertility preservation are limited by parental consent and financial support. Healthcare teams should have multiple conversations with minors and their parents to discuss options and hopefully reach a satisfactory solution for all. Reaching an acceptable solution for the parents and the child should be the primary goal of the healthcare team. However, it can be reasoned that the patient's satisfaction has priority over the parents' satisfaction. More research is needed on transgender youths' ability to regain or preserve fertility in adulthood if they are unable to access preservation services as minors.

BLINDING OF THE CASE

Details of this case have been altered to protect the identity of the patient and family.

NOTES

1. N. Teper, "When Parents Disagree on Medical Care for Their Children," *Law-Related Reflections,* 29 August 2013, *https://teperlaw.wordpress.com/2013/08/29/when-parents-disagree-on-medical-care-for-their-children/.*

2. C.M. Peterson et al., "Suicidality, Self-Harm, and Body Dissatisfaction in Transgender Adolescents and Emerging Adults with Gender Dysphoria," *Suicide and Life Threatening Behavior* 47, no. 4 (2017): 475-82.

3. Ibid.

4. E. Coleman et al., "Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7," *International Journal of Transgenderism* 13, no. 4 (2012): 165-232; W.C. Hembree et al., "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," *Journal of Clinical Endocrinology & Metabolism* 102, no. 11 (2017): 3869-903.

5. Ethics Committee of the American Society for Reproductive Medicine,"Fertility Preservation and Reproduction in Cancer Patients," *Fertility and Sterility* 83, no. 6 (2005): 1622-3.

6. S.J. Lee et al., "American Society of Clinical Oncology Recommendations on Fertility Preservation in Cancer Patients," *Journal of Clinical Oncology* 24, no. 18 (2006): 2917-31.

7. K. Oktay et al., "Fertility Preservation in Patients with Cancer: Asco Clinical Practice Guideline Update," *Journal of Clinical Oncology* 36, no.19 (2018): 1994-2001.

8. A. Goodman, "Oncofertility for Adolescents: When Parents and Physicians Disagree About Egg Cryopreservation for a Mature Minor," *AMA Journal of Ethics* 17, no. 9 (2015): 826.

9. J.N. Hudson et al., "New Promising Strategies in Oncofertility," *Expert Review of Quality of Life in Cancer Care* 2, no. 2 (2017): 67-78.

10. J. Kutner, "This Is How Transgender Women Are Becoming Moms in 2016," *Mic,* 9 February 2016, *https://mic.com/articles/124495/this-is-how-transgender-women-are-becoming-moms-in-2016#.SVycLPptJ.*

11. L. Campo-Engelstein, "Consistency in Insurance Coverage for Iatrogenic Conditions Resulting from Can-cer Treatment Including Fertility Preservation," *Journal of Clinical Oncology* 28, no. 8 (2010): 1284-6.

12. B.H. Luk and A.Y. Loke, "The Impact of Infertility on the Psychological Well-Being, Marital Relationships, Sexual Relationships, and Quality of Life of Couples: A Systematic Review," *Journal of Sex and Marital Therapy* 41, no. 6 (2015): 610-25.

13. K. Wierckx et al., "Reproductive Wish in Transsexual Men," *Human Reproduction* 27, no. 2 (2011): 483-7.

14. *A Survey of LGBT Americans* (Washington, D.C.: Pew Research Center, 2013).

15. L. Nahata et al., "Fertility Preservation for a Transgender Teenager," *Pediatrics* 142, no.3 (2018): e20173142; D. Chen et al., "Fertility Preservation for Transgender Adolescents," *Journal of Adolescent Health* 61, no. 1 (2017): 120-3.

16. L. Nahata et al., "Low Fertility Preservation Utilization among Transgender Youth," *Journal of Adolescent Health* 61, no. 1 (2017): 40-4; Diane Chen et al., "Fertility Preservation for Transgender Adolescents," *Journal of Adolescent Health* 61, no. 1 (2017): 120-3.

17. G.P. Quinn et al., "Preserving the Right to Future Children: An Ethical Case Analysis," *American Journal of Bioethics* 12, no. 6 (2012): 38-43.

18. L. Stack, "Texas Bill Would Let Adoption Agencies Reject Families on Religious Grounds," *New York Times,* 11 May 2017.

19. C. Finlayson et al., "Proceedings of the Working Group Session on Fertility Preservation for Individuals with Gender and Sex Diversity," *Transgender Health* 1, no. 1 (2016): 99-107.

20. R. Palmer and G. Gillespie, "Consent and Capacity in Children and Young People," *Archives of Disease in Childhood: Education & Practice* 99, no. 1 (2014): 2-7.

21. M.A. McCabe, "Involving Children and Adolescents in Medical Decision Making: Developmental and Clinical Considerations," *Journal of Pediatric Psychology* 21, no. 4 (1996): 505-16.

22. E.K. Johnson and C. Finlayson, "Preservation of Fertility Potential for Gender and Sex Diverse Individuals," *Transgender Health* 1, no. 1 (2016): 41-4; Nahata et al., "Low Fertility Preservation Utilization," see note 16 above.

23. B.A Sisk et al., "Navigating Decisional Discord: The Pediatrician's Role When Child and Parents Disagree," *Pediatrics* 139, no. 6 (2017): e2017 0234.

24. J. Bester and E. Kodish, "Children Are Not the Property of Their Parents: The Need for a Clear Statement of Ethical Obligations and Boundaries," *American Journal of Bioethics* 17, no. 11 (2017): 17-9.

25 S.S. Hendon, "In Re: Jns Case No F17-334x Judicial Entry," news release, 2018, *https://www.scribd.com/ document/371667957/Ruling-from-Judge-Sylvia-Sieve- Hendon-on-transgender-boy#.*

26 C.M. Peterson et al., "Suicidality, Self-Harm, and Body Dissatisfaction in Transgender Adolescents and Emerging Adults with Gender Dysphoria," *Suicide and Life-Threatening Behavior* 47, no. 4 (2017): 475-82.

27. A.E. Eyler, S.C. Pang, and A. Clark, "LGBT Assisted Reproduction: Current Practice and Future Possibilities," *LGBT Health* 1, no. 3 (2014): 151-6.

28. A.D. Light et al., "Transgender Men Who Experienced Pregnancy after Female-to-Male Gender Transitioning," *Obstetrics Gynecology* 124, no. 6 (2014): 1120-7.

Proxy Consent by a Physician When a Patient's Capacity Is Equivocal: Respecting a Patient's Autonomy by Overriding the Patient's Ostensible Treatment Preferences

Abraham Graber, Carolyn April, and Michael D. April

ABSTRACT

Respect for patients' autonomy has taken a central place in the practice of medicine. Received wisdom holds that respect for autonomy allows overriding a patient's treatment preferences only if the patient has been found to lack capacity. This understanding of respect for autonomy requires a dichotomous approach to assessing capacity, whereby a patient must be found either to have full capacity to make some particular treatment decision or must be found to lack capacity to make that decision. However, clinical reality is more complicated, and, in borderline cases, different physicians may arrive at disparate judgments of capacity. In such cases, when capacity-determination protocols fail to achieve consensus, physicians would benefit from guidance regarding the clinical decision-making process necessary to elucidate the most ethically sound course of action. This article considers one such case and argues that, in a limited number of cases, respect for autonomy may require overriding a patient's stated treatment preference when a capacity determination is equivocal, even though the patient has not clearly demonstrated a lack of capacity.

Abraham Graber, PhD, is Director of Medical Humanities and Assistant Professor of Philosophy at the University of Texas, San Antonio, San Antonio, Texas. *agraber@gmail.com*
Carolyn April, MD, DPhil, is an Assistant Professor at University of Texas Health Science Center at San Antonio, Department of Medicine, Division of General & Hospital Medicine.
Michael D. April, MD, DPhil, MSc, MAJ, USA, MC, is an Assistant Professor of Emergency Medicine at the Uniformed Services University of Health Sciences in Bethesda, Maryland; an Adjunct Assistant Professor of Emergency Medicine at Baylor University in Waco, Texas; and Assistant Program Director for Research, Emergency Medicine Residency, at the San Antonio Uniformed Services Health Education Consortium in San Antonio.

INTRODUCTION

Respect for patients' autonomy requires honoring their healthcare preferences. Received wisdom holds that these preferences can be overridden only if patients have been found to lack capacity. We will argue, *contra* the received view, that in a limited range of cases physicians best respect patients' autonomy by overriding treatment preferences *even though* the patients have not definitively demonstrated a lack of capacity.

BACKGROUND

Principlism holds that a physician's moral responsibilities are determined by the appropriate balance of four (potentially competing) moral principles: respect for autonomy, beneficence, nonmaleficence, and justice.[1] Although ortho-

doxy holds that each of the principles carries equal weight,[2] respect for autonomy has become *de facto* "first among equals."[3]

Autonomy requires that one be "free from both controlling interference by others and limitations that prevent meaningful choice. . . ."[4] Lack of decision-making capacity is one type of limitation that can "prevent meaningful choice." Capacity "includes the ability to: 1. Receive information 2. Process and understand information 3. Deliberate [and] 4. Make, articulate, and defend choices."[5]

Capacity is not an absolute property that applies across all decisions. Rather, an individual may have capacity to make some healthcare decisions but lack capacity to make others: "DMC [decision-making capacity] is a dynamic, task-specific, and changing talent . . . pertaining to the particular health care decisions at hand. Often, impairment is situational; the same patient may be competent for one decision and not another."[6]

When a patient lacks capacity to make some healthcare decision, the decision should be made by an informed proxy.[7] Ideally, a patient's family member or guardian will serve as proxy decision maker. However, if neither are available and the need for intervention is urgent, the treating physician may provide proxy consent using the *best interest standard*. The best interest standard justifies proxy consent when a medical intervention would be in a patient's best interest and the patient lacks capacity to make her or his own autonomous healthcare decisions.[8]

It is generally thought that proxy consent is only permissible when a patient has been found to lack capacity. For this reason, it is important to accurately determine whether a patient has capacity to make a particular healthcare decision.[9] An attending physician generally makes this determination using a semistructured interview containing open-ended questions.[10] In equivocal cases, a psychiatry consult is warranted.[11] Neither the literature nor our local hospital protocols offer recommendations for how to proceed if a capacity determination remains equivocal after following these procedures.

We will argue that, in a limited number of cases in which the determination of capacity is equivocal, physicians may actually best respect a patient's autonomy by overriding the patient's stated treatment preferences. Our discussion focuses on the following anonymized case study, drawn from an attending physician's (CWA's) experience at an urban tertiary care hospital.

CASE STUDY

Frank, a man in his mid-40s, presented to the emergency department (ED) complaining of difficulty breathing. Although no healthcare records were available, Frank informed hospital staff that he had HIV/AIDS and was not currently receiving antiretroviral or antibiotic prophylactic treatment. His vital signs demonstrated profound hypoxia and he immediately required substantial supplemental oxygen (100 percent oxygen delivered by face mask). Chest radiography was consistent with pneumonia. It was judged likely that Frank's low oxygen levels were caused by an infection that was potentially curable with antimicrobial medications. All of the physicians involved in his initial care recommended that Frank undergo urgent endotracheal intubation and mechanical ventilation to improve his chances of surviving long enough for antimicrobials to cure the infection. Frank did not decline supplemental oxygen or antimicrobial medications, but he refused intubation and mechanical ventilation. With some reservations, the initial the ED physicians judged that Frank had capacity to refuse intubation. The ED team therefore anticipated a course of limited care and sought admission to a general medicine floor rather than an intensive care unit (ICU) equipped to care for ventilated patients.

When interviewed by the general medicine admitting team, Frank intermittently removed his oxygen mask, causing his oxygen levels to drop into the seventies, a level that can cause confusion and can be imminently life threatening. While Frank was able to repeat the different therapeutic choices available to him, his refusal of intubation was at odds with his other stated preferences: despite refusing intubation and expressing an understanding that he would likely die if he was not intubated, Frank also expressed a desire to live and a desire to "see the sun again." Perhaps unsurprisingly given his critical illness, Frank's engagement with the general medicine team was intermittent.

Following the team's evaluation, the general medicine attending judged, with some hesitation, that Frank lacked capacity to refuse intubation and mechanical ventilation. The general medicine team discussed this concern with the ED team. The two teams acknowledged that de-

termining capacity in this patient was challenging; given the different determinations reached by the two teams and the stakes of the intubation decision, the ED and the general medicine teams agreed to consult psychiatry to solicit a definitive opinion regarding Frank's capacity. However, when the psychiatry team arrived, Frank did not participate in their evaluation, and thus the psychiatry team stated that they could not draw any conclusion regarding whether he had capacity to refuse intubation or not. The general medicine team did not have the procedural skills to intubate Frank themselves, and the ED team, who were qualified to intubate, believed Frank had autonomously declined intubation, and thus refused to assist with intubation. Frank did not undergo intubation. He underwent admission to general medicine and died shortly thereafter.

Given the failure of the usual capacity assessment protocol to reach a clear judgment regarding Frank's capacity, and given the urgency and the high stakes of the case, the teams might have best honored their shared commitment to respect Frank's autonomy by overriding his expressed (but not clearly capacitated) refusal and intubating him. The remainder of this article will build a theoretical justification of this position that has broader implications for thinking about capacity.

THE SLIDING SCALE AND EQUIVOCAL CAPACITY

Frank's final visit to the hospital gives rise to a range of ethical concerns. The central question is: Should Frank have undergone intubation? Although there was disagreement between the ED team and the general medicine team, the authors are of the opinion that the answer to this question is an unequivocal "Yes."

It is widely accepted that the standards for capacity vary depending on the implications of the decision being made.[12] For example, greater evidence of capacity should be required for a patient who expresses a wish to forego a lifesaving treatment than for a patient who expresses a wish to not take analgesic ibuprofen. This view, that the standards for capacity vary dependent on the implications of a treatment decision, is known as *the sliding scale* account of capacity.

The sliding scale account of capacity is generally justified by a trade-off between the principles of autonomy and beneficence.[13] As the potential harm of a treatment decision increases, the principle of beneficence becomes increasingly salient. As the principle of beneficence becomes increasingly salient, the principle of autonomy must similarly gain stature if it is to trump beneficence. Thus, the greater the potential harm of a treatment decision, the more demanding the standards for evidence of capacity.

The application of the sliding scale to Frank's case seems relatively straightforward. Frank's stated desire is to forego intubation. In the case at hand, not only is intubation likely to be short lived, but also, deciding not to undergo intubation is tantamount to deciding to die. Thus, in order to be capacitated to refuse intubation, a sliding scale demands significant evidence of Frank's capacity. Yet the available evidence is equivocal. It is thus plausible that Frank has failed to adequately demonstrate the level of capacity required to refuse lifesaving treatment. The application of the sliding scale to the case at hand appears to yield the result that Frank lacks capacity to refuse treatment and should thus have undergone intubation.

The authors are sympathetic with this analysis of Frank's case. Indeed, in attempting to convince the ED team to intubate Frank, the general medicine team highlighted the above considerations. The ED team remained unmoved.

At one level it is attractive to hold that Frank's death was the result of nothing more than an inaccurate judgment on the part of the ED team. The ED team wrongly judged that Frank was competent; had they made the correct assessment of Frank's capacity, he would still be alive. Yet ethics is fundamentally about reasons for action. If all that can be said is that the ED team made an inaccurate assessment of Frank's capacity, we are left without any additional tools for navigating similar cases in the future. We should thus demand that clinical ethics do more than answer the question: Should Frank have undergone intubation? An adequate clinical ethics should further provide guidance for careproviders who find themselves in cases relevantly similar to our case study.

There is voluminous literature on (1) how to determine if a patient has capacity and (2) appropriate clinical behavior when a patient lacks capacity. Shared throughout this literature is the implicit assumption that the totality of evidence will indicate that a patient either does or does not have capacity. The conversations

about Frank's capacity were constrained by this implicit assumption. The central question considered by the involved parties was: Does the evidence clearly indicate that Frank has the capacity to refuse intubation? However, there is a third option. The evidence may be equivocal. It may be that, even after taking the sliding scale into account, the evidence neither clearly indicates that Frank has capacity nor clearly indicates that Frank lacks capacity.

Cases in which the evidence for capacity is equivocal are unavoidable. Evidence for capacity falls on a spectrum, with clear evidence for capacity at one end and clear evidence for lack of capacity at the other end. In between these ends of the spectrum are cases in which there is some evidence for capacity and some evidence for lack of capacity. At the middle point of the spectrum the evidence is entirely indeterminate, giving one neither reason to believe that a patient has capacity nor reason to believe that a patient lacks capacity. The application of the sliding scale does not fundamentally change this analysis. By the lights of the sliding scale, the requirements for capacity change concomitant with the seriousness of the consequences of any given decision. The sliding scale will thus move where the bar for capacity falls on the spectrum. Yet wherever on the spectrum one sets the bar for capacity, evidence for capacity will still fall on a spectrum and, consequently, there will still be cases in which the totality of evidence remains equivocal.

While evidence for capacity may fall on a spectrum, intervention decisions are binary: either patients will undergo an intervention, or they will not. For pragmatic reasons, it may thus seem important to take a binary approach to assessing capacity. If Frank has capacity to refuse treatment, he should not be intubated and will, consequently, die. By contrast, if Frank lacks capacity to refuse treatment, he should be intubated, and will likely live. These are high-stakes decisions and there is no middle ground. Given that, medically, there is no intermediate position, it seems that our judgments about capacity must also admit of no degrees.

A *prima facie* clinical challenge is presented by the fact that evidence of capacity falls on a spectrum whereas intervention decisions are binary. This clinical challenge is resolved by holding that, in cases in which evidence regarding a patient's capacity is inconclusive, in deference to the patient's autonomy, the patient should be presumed to possess capacity.[14] This presumption allows a binary approach to determining capacity. Cases in which capacity is equivocal are treated like cases in which a patient has clearly demonstrated capacity.

There are two distinct reasons to treat cases of equivocal capacity as instances in which a patient has capacity. First, decisions regarding interventions are binary; the patient either will or will not undergo the intervention. The received view provides a protocol for making binary decisions in instances when it is unclear whether a patient has capacity. Second, treating cases of equivocal capacity as instances in which a patient is clearly capacitated respects the patient's autonomy by shielding the patient from undue interference by physicians in the decision-making procedure.

Given that these distinct rationales support treating cases in which evidence for capacity is equivocal as instances in which a patient has capacity, under what conditions should we reconsider our approach to equivocal capacity? The binary demands of clinical decision making and the moral imperative to respect patients' autonomy are both nonnegotiable. It nonetheless remains unclear whether current practice regarding equivocal capacity best meets these two criteria. We should reconsider our approach to equivocal capacity if there is some other approach that (1) supports a binary approach to clinical decision making and (2) better respects patients' autonomy.

For the remainder of the article we will assume that clinical evaluations of Frank's capacity were equivocal. That is, we will assume that clinical evaluations of Frank's capacity give us no more reason to believe that Frank has capacity than they give us reason to believe that Frank lacks capacity. As noted in our discussion of the sliding scale of capacity, we do not believe that this assumption reflects the clinical reality. Nevertheless, there are good reasons for making this assumption. Although perhaps not theoretically accurate, in Frank's case this assumption fits the *de facto* clinical reality. The ED team was not responsive to the evidence that indicated Frank's lack of capacity. Although at the theoretical level it may be adequate to note that the ED team made a mistake and incorrectly judged that Frank had capacity, at the clinical level something actionable was required. The extensive literature on capacity nearly exclusively focuses on two issues: (1) how to determine whether a patient has

capacity and (2) the ethical implications of a determination of capacity or its absence. This leaves unaddressed cases in which evidence for capacity is equivocal. Consequently, when Frank's physicians could not achieve consensus regarding Frank's capacity, there were no further avenues for discussion. Had the bioethicists' approach to capacity facilitated discussions regarding how to approach cases of equivocal capacity, the general medicine team and the ED team could have had these conversations and, consequently, Frank might still be alive.

In cases of equivocal capacity, standard practice would have us treat patients as if they had capacity. We will consider another approach. Having assumed that the evidence regarding Frank's capacity was equivocal, we will ask two distinct questions. First we will ask, "What was the magnitude of threat to Frank's autonomy posed by each intervention decision?" Second we will ask, "What was the likelihood that each intervention decision would have infringed on Frank's autonomy?" Once we have answers to each of these questions, we will show that the answers to these two questions can inform binary clinical decision making. We will further argue that, rather than treating Frank as if he clearly had capacity, Frank's physicians would have best respected his autonomy had their decisions regarding his care been guided by the answers to these two questions.

THE CASE FOR RESPECTING FRANK'S AUTONOMY BY OVERRIDING HIS TREATMENT PREFERENCE

The Magnitude of the Harm of Overriding Frank's Treatment Preference

What were the implications of overriding Frank's expressed desire not to undergo mechanical ventilation? Assuming that Frank had the capacity to refuse treatment, overriding his stated treatment preference would have been a violation of Frank's autonomy. Nevertheless, while it is important not to understate this harm, it is also important not to overstate it. While some intubated patients may remain on life support indefinitely,[15] Frank's relative youth and the treatable nature of his acute illness made it very likely that he would have only remained on mechanical ventilation for a short period of time. Furthermore, even if his physicians had determined that it would have been in Frank's best interest to remain on life support for a longer period of time, mechanical ventilation might have reversed Frank's low blood oxygen level, thus potentially restoring his full capacity and allowing him to decide for himself, clearly and without ambiguity, whether to continue life support. Consequently, although intubation risks infringed on Frank's autonomy, the magnitude of the threat was relatively small, as the intervention was likely to be short-lived and could have been reversed if Frank had clearly regained capacity.

The Magnitude of the Harm of Respecting Frank's Treatment Preference

Assuming Frank lacked capacity, a refusal to override his treatment preference would have constituted a violation of his autonomy. If patients lack capacity to make their own healthcare decisions, these decisions should be made by an informed proxy. Consequently, on the assumption that Frank lacked capacity to refuse treatment, failure to allow a proxy to make his healthcare decisions constituted a violation of established procedures for protecting a patient's autonomy and well-being.

More importantly, the failure to intubate Frank resulted in his death. In addition to preserving present autonomy, protection of future autonomy is an important consideration when making healthcare decisions.[16] Death deprives patients of the opportunity for any future decisions, preventing them from ever exercising their autonomy again. If Frank lacked capacity to refuse intubation, respecting his stated treatment preference was tantamount to denying Frank any future opportunity to make autonomous decisions. Refusing to intubate Frank threatened his immediate autonomy by denying him the opportunity to have his decision made by an informed proxy. More importantly, it further posed a significant and long-term threat to his autonomy by effectively preventing him from making any future decisions.

Probability of Capacity

In addition to considering the magnitude of potential harm to Frank's autonomy, we must further consider the likelihood of these harms occurring. If Frank made the informed and capacitated decision to refuse intubation, then we should not consider his subsequent death an

infringement on his autonomy. Similarly, if Frank lacked capacity to refuse intubation, then we should not consider forced intubation an infringement on his autonomy. Thus, in considering the likelihood of the above harms occurring, we must consider the likelihood that Frank had capacity.

Thus far, we have assumed that clinical evidence regarding Frank's capacity was perfectly equivocal, providing equally good support to the hypothesis that Frank had capacity and to the hypothesis that he lacked capacity. In the following discussion, we continue to accept this assumption. However, in instances when the totality of clinical evidence does not clearly indicate capacity or its absence, theoretical considerations may nonetheless slightly favor one hypothesis over the other. Such theoretical considerations do not constitute grounds for an all-things-considered judgment regarding Frank's capacity. An informed judgment regarding capacity must be made on the basis of clinical evidence. Theoretical considerations can, however, marginally shift the totality of the evidence. Thus, if the clinical evidence is perfectly equivocal, theoretical considerations may be able to shift the balance so that, if forced to give odds, we could, for example, give a 51 percent probability (after the application of the sliding scale) to the hypothesis that Frank lacked capacity and a 49 percent probability (after the application of the sliding scale) to the hypothesis that Frank possessed capacity. Such evidential shifts are, as a general rule, too minor to turn an instance of equivocal capacity into a clear instance of capacity (or its absence). These minor evidence shifts can, however, be relevant when asking the question: What is the likelihood that Frank had capacity?

When obtaining informed consent, physicians face a significant theoretical challenge. On one hand, it is essential that physicians provide information adequate for a patient to make an informed decision. On the other hand, pragmatic constraints prevent physicians from providing exhaustive information on every potential benefit and harm of every possible treatment. Thus, obtaining informed consent requires that physicians appropriately balance the informational needs of the patient and the pragmatic demands of practice.[17] Which information must physicians disclose? Informed consent requires that physicians provide all information that a "reasonable person" would want to know.[18]

The reasonable person standard allows physicians to make the (defeasible) assumption that patients are reasonable persons.[19] Given the limited duration of the intervention and the clear benefits of intubation, it seems clear that a reasonable person in Frank's situation would have chosen to undergo intubation and life support. By contrast, Frank refused intubation. This dissonance may mean one of two things: Frank had unarticulated reasons for refusing mechanical ventilation that the average reasonable person lacked *or* Frank was analogous to the average reasonable person, but, at that time, lacked capacity to make his own healthcare decisions. Frank's refusal of mechanical ventilation was not, by itself, evidence one way or another.[20] There was, however, an additional piece of evidence. Frank had hypoxia, a condition that can hamper decision making. Thus, against the background assumptions that (1) Frank was a reasonable person and (2) the reasonable person in Frank's situation would have chosen intubation, Frank's refusal of a lifesaving treatment, combined with his severe hypoxia, give us reason to suspect that Frank may have lacked capacity.

Given equivocal clinical evidence, no confident judgment regarding Frank's capacity could be made. Nonetheless, theoretical considerations like the above can marginally shift our assessment of the evidence. While the totality of evidence was not sufficient to secure agreement among the physicians involved in his case, theoretical considerations provide some (minor) evidence in favor of the hypothesis that Frank lacked capacity.

Respecting Frank's Autonomy

The fact that the two teams evaluating Frank disagreed on his capacity to make decisions and the fact that the protocol to determine capacity failed to lead to a clear judgment indicates that despite the clinicians' best attempts to honor the theoretical ideal of respecting capacitated treatment decisions, sometimes clinical reality precludes clear determination of capacity. Rather than attempt to force Frank into one capacity category or the other, we have suggested that it may be more helpful for physicians to acknowledge that some cases are ambiguous. In so doing, physicians may more easily accept that there is uncertainty about which course of action Frank would autonomously choose, and thus proceed by considering which option had the

lowest attendant risk of compromising Frank's autonomy.

In considering which option had the lowest attendant risk of compromising Frank's autonomy, we must consider two factors: the magnitude of risk to Frank's autonomy and the probability that these risks might have been realized. First we will consider the question of probability. Although the totality of available evidence might not have permitted a confident judgment regarding capacity, the evidence might have nonetheless marginally favored one hypothesis over the other. In cases of equivocal capacity, we should first ask: Considering all things equally, did the evidence skew in the direction of capacity or lack of capacity?

Although the evidence regarding Frank's capacity to refuse treatment was equivocal, we believe it nonetheless leaned slightly in the direction of Frank's lacking capacity to refuse intubation. Consequently, if the implications for Frank's autonomy were equivalent for the decision to intubate and the decision not to intubate, we ought to have intubated. Under such conditions, the decision to intubate would have maximized the probability of respecting Frank's autonomy.

We must further consider the magnitude of the impact of potential clinical decisions on Frank's autonomy. In this instance, the decision to treat Frank risked a significant violation of Frank's autonomy; however, the magnitude of the harm was mitigated by the likelihood that, if intubated, Frank would shortly have been able to make a clearly capacitated judgment regarding the continuation of mechanical ventilation. By contrast, the decision not to treat Frank posed a dual threat to Frank's autonomy. First, on the assumption that Frank lacked capacity, following his stated preference would have infringed on his autonomy by not giving him the opportunity to have his treatment made by an appropriate proxy. More importantly, because Frank needed intubation to survive, the decision not to intubate led to his death and thereby prohibited Frank from making any future decisions. If Frank having capacity and Frank lacking capacity were both equally probable, his autonomy would have been best respected had he been intubated, as this was the decision with the least attendant risk to Frank's autonomy.

At the outset of this section we argued that the current practice regarding cases of equivocal capacity should be revised if there is some other option that (1) allows for binary clinical decision making while (2) better respecting patients' autonomy. We have now suggested that, rather than treating cases in which the evidence for a patient's capacity is equivocal in the same way we treat cases in which there is clear evidence for capacity, in equivocal cases we should ask: What best respects the patient's autonomy? In answering this question, we should consider both the probability and magnitude of potential harms to the patient's autonomy. When this approach was applied to Frank's case, we found that both considerations indicated that Frank should have been intubated. Overriding his stated preference and proceeding with intubation would have best respected Frank's autonomy.

In arriving at this conclusion, we have simultaneously demonstrated that the proposed approach to cases in which evidence for capacity is equivocal meets both (1) and (2) above. First, it offers a binary method for clinical decision making. About any given intervention, we can ask: Does this best respect the patient's autonomy (when this is understood to be a question about the probabilities and magnitudes of harms to autonomy)? If the answer is "Yes, this intervention best respects the patient's autonomy," then we have reason to proceed with the intervention. If the answer is "No, this intervention does not best respect the patient's autonomy," then we have reason not to proceed with the intervention.

Second, as we argued in our analysis of Frank's case, this approach to cases of equivocal capacity may better respect patients' autonomy than current practice. If we accept the assumption that evidence for Frank's capacity was equivocal, current practice would have us treat him as if he were clearly capacitated. We have argued that his autonomy would have been better respected had physicians made the intervention decision based on consideration of the probabilities and magnitudes of potential harms to Frank's autonomy.

There is a real possibility that Frank genuinely wished to avoid intubation even at the expensive of his life and that he had the capacity to make this decision. In advocating that Frank's stated treatment preferences should have been overridden, it is important to admit the genuine potential for real harm that was associated with intubation. There are, however, very real harms associated with all of the options that

were available. The best we can do is to consider all of the intervention options and form a considered judgment about how to proceed. That said, it merits emphasizing that while we can do no better than to act in line with our best judgments, it is also the case that sometimes our best judgments are wrong.

We have now argued that Frank's autonomy would have been best respected by overriding his stated wishes and proceeding with intubation. This conclusion contrasts with the received understanding of how careproviders ought to approach cases of equivocal capacity. With the aim of prioritizing patients' autonomy, current wisdom holds that patients must *clearly demonstrate a lack of capacity,* as opposed to merely failing to demonstrate capacity, in order for healthcare providers to override their healthcare decisions.[21] Cases like Frank's demonstrate that, in some instances when the evidence for capacity is equivocal, a patient's autonomy may be best respected by overriding the patient's stated treatment preference, even though the patient does not clearly demonstrate a lack of capacity.

Beyond Frank

We have now argued that Frank's autonomy would have been best respected by intubating him despite his stated (but not clearly capacitated) desire to the contrary. This is an important result because it challenges the current assumption that a patient's autonomy is best respected by treating paradigm cases of capacity and cases of equivocal capacity similarly. Nonetheless, although Frank's case may challenge the received view regarding best practice in cases of equivocal capacity, significant theoretical and empirical work remains to be done to develop new clinical protocols to guide healthcare providers in cases of equivocal capacity.

The lessons of Frank's case are likely to apply to a variety of cases in which capacity is equivocal and some or all of the following conditions are met:

- The nonpreferred healthcare decision involves an acute intervention or can be easily reversed;
- The preferred healthcare decision would considerably and irreversibly restrict the patient's future autonomy;
- The patient's healthcare decision is contrary to what a reasonable person would choose;
- The patient has an acute condition that has the potential to impair cognitive function, for example, hypoxia, septic shock, bacterial meningitis, severe hyponatremia, or hepatic encephalopathy;
- Healthcare providers do not have access to an advance directive or other evidence of the patient's treatment preference when the patient was capacitated.

Future work should (1) further develop and systematize a list of clinical considerations that are relevant to respecting patients' autonomy when evidence for the patient's capacity is equivocal, as well as (2) attempt to develop protocols for weighing the relevance of each of the above considerations when deciding what best respects a patient's autonomy.

OPENING THE DOOR TO PARENTALISM?

Contemporary medical ethics is, rightly, characterized by a strong antiparentalist bent. Parentalism is a perennial concern any time there is discussion of healthcare providers overriding a patient's stated treatment preferences. Is the preceding discussion problematically parentalistic?

There are at least two ways in which our proposal could be problematically parentalistic. By failing to put appropriate emphasis on patients' autonomy, it could be problematically parentalistic at the theoretical level. Alternatively, the proposal could be theoretically unproblematic, but could be problematic because, at the level of application, it undermines safeguards against parentalism. We will consider each concern in turn.

We have argued that, in some cases when a lack of capacity has not been demonstrated, a patient's autonomy is best respected by overriding the patient's stated treatment preference. By making the autonomy of the patient the central value, our argument is, at least at the theoretical level, antiparentalist. There should thus be no concern that, at the theoretical level, our proposal is problematically parentalistic.

There is, however, room for concern that we are opening the door to parentalism at the practical level. Safeguarding the autonomy of patients while also valuing their well-being requires striking a careful balance between the authority of physicians and the power of patients to make their own decisions. One may be concerned that, in allowing healthcare providers to

override the preferences of a patient in the absence of a demonstrated lack of capacity, one shifts this balance too far in the direction of physicians' authority.

While this concern is well taken, it is unlikely to be relevant to the kinds of cases under consideration, that is, cases in which the evidence for a patient's autonomy is equivocal. To see why, reconsider the ED team's decision that Frank possessed capacity to refuse intubation. Note that there was effectively nothing, from an administrative or enforcement perspective, that would have prevented the ED team from making the opposite determination. A few words written in Frank's chart was all it would have taken for the ED team to justify the finding that Frank lacked capacity. In cases when a patient's capacity is equivocal, power already lies almost entirely with the physician. Consequently, there should be little concern that, at the level of application, our proposal is problematically parentalistic. In the relevant cases, at the practical level, physicians already possess all of the power. Consequently, once it has been judged that evidence regarding a patient's capacity is equivocal, implementation of our proposal would not further shift power in the direction of the physician.

There is, however, room for further concern regarding the parentalistic potential of our proposal. We have argued that, in some cases when a patient's autonomy is equivocal, a patient's interests are best respected by overriding her or his stated but not clearly capacitated treatment preferences. On the assumption that we can correctly identify cases in which the evidence for capacity is equivocal, there is no reason at either the theoretical or practical level to be concerned that our proposal is problematically parentalistic. We should not, however, take a blasé attitude toward the assumption that we can correctly identify cases in which the evidence for capacity is equivocal. If cases of clear capacity are treated as instances of equivocal capacity, implementation of our proposal could lead to deeply problematic parentalistic practices.

In order to guard against parentalism, some method is needed to determine when evidence for capacity is truly equivocal. Developing such a protocol falls well outside the bounds of this article. It is, however, an essential step in moving from consideration of Frank's case to providing generalized clinical recommendations. We thus endorse caution. If a protocol can be developed that allows physicians to readily identify cases in which evidence for capacity is truly equivocal, respecting patients' autonomy likely requires a revision to current practice. If, however, no such protocol can be developed, it may be best to settle with the *status quo.*

CONCLUSION

Failure to demonstrate a patient's decisional capacity is not generally thought to be sufficient to permissibly override a patient's healthcare preferences. Instead, the ethical justification for overriding a patient's refusal of an intervention relies on the patient clearly demonstrating a lack of capacity. Drawing on a case study, we have argued that this binary view fails to capture the complexity of determining a patient's capacity in challenging cases when the determination of a patient's capacity is equivocal. Furthermore, we have argued that by relying on an over simplified binary view of capacity, it is possible to undermine a patient's autonomy by respecting the patient's preferences when the capacity underlying those preferences is equivocal. We suggest that in such equivocal cases, physicians can acknowledge the uncertainty of a patient's capacity and strive to implement the treatment option that poses the least overall risk to the patient's autonomy. In at least some cases, respecting patients' autonomy may require overriding their stated but not clearly capacitated healthcare preferences, even though the patients did not clearly demonstrate a lack of capacity.

BLINDING OF THE CASE

Some elements of the case have been altered to protect the identity of the patient.

NOTES

1. T.L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics,* 7th ed. (New York: Oxford University Press, 2012).

2. Ibid.

3. R. Gillon, "Ethics Needs Principles—Four Can Encompass the Rest—and Respect for Autonomy Should Be 'First among Equals,' " *Journal of Medical Ethics* 29, no. 5 (2003): 307-12.

4. Beauchamp and Childress, *Principles of Biomedical Ethics,* see note 1 above, p. 58.

5. G.L. Larkin, C.A. Marco, and J.T. Abbott, "Emergency Determination of Decision-Making Capacity: Balancing Autonomy and Beneficence in the Emergency Department," *Academic Emergency Medi-*

cine 8, no. 3 (2001): 282-4, 282.

6. Ibid., 282; J.P. Demarco, "Competence and Paternalism," *Bioethics* 16, no. 3 (2002): 231-45; L. Ganzini et al., "Ten Myths about Decision-Making Capacity," *Journal of the American Medical Directors Association* 5, no. 4 (2004): 263-7.

7. Beauchamp and Childress, *Principles of Biomedical Ethics,* see note 1 above.

8. R. O'Neil, "Determining proxy consent," *Journal of Medicine and Philosophy* 8, no. 4 (1983): 389-403.

9. P.S. Appelbaum, "Assessment of Patients' Competence to Consent to Treatment," *New England Journal of Medicine* 357, no. 18 (2007): 1834-40; A. Buchanan, "Mental Capacity, Legal Competence and Consent to Treatment," *Journal of the Royal Society of Medicine* 97, no. 9 (2004): 415-20.

10. Ibid.

11. Ibid.

12. Appelbaum, "Assessment of Patients' Competence," see note 9 above.

13. Ibid.

14. Ibid.; G. Hartogh, "Do We Need a Threshold Conception of Competence?" *Medicine, Health Care and Philosophy* 19, no. 1 (2016): 71-83.

15. C.C. Hook and P.S. Mueller, "The Terri Schiavo Saga: The Making of a Tragedy and Lessons Learned," *Mayo Clinic Proceedings* 80, no. 11 (2005): 1449-60; N. Jecker, L. Schneiderman, and A.R. Jonsen, "Medical Futility: Its Meaning and Ethical Implications," *Annals of Internal Medicine* 112, no. 12 (1990): 949-54.

16. D. Davis, "Genetic Dilemmas and a Child's Right to an Open Future," *Hastings Center Report* 27 (1997): 7-15; J. Feinberg, "The Child's Right to an Open Future," in *Whose Child? Children's Rights, Parental Authority, and State Power,* ed. W. Aiken and H. LaFollette (Totowa, N.J.: Littlefield, Adams, 1980), 124-53.

17. B. Murray, "Informed Consent: What Must a Physician Disclose to a Patient?" *Virtual Mentor* 14, no. 7 (2012): 563; L. Pass and A.D. Graber, "Informed Consent, Deaf Culture, and Cochlear Implants," *The Journal of Clinical Ethics* 26, no. 3 (Fall 2015): 219-30.

18. Murray, "Informed Consent," see note 17 above; *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

19. O'Neil, "Determining Proxy Consent," see note 8 above.

20. Ganzini et al., "Ten Myths," see note 6 above.

21. Appelbam, "Assessment of Patients' Competence," see note 9 above; Hartogh, "Do We Need a Threshold Conception," see note 14 above.

Training to Increase Rater Reliability When Assessing the Quality of Ethics Consultation Records with the Ethics Consultation Quality Assessment Tool (ECQAT)

Robert Allan Pearlman, David Alfandre, Barbara L. Chanko, Mary Beth Foglia, and Kenneth A. Berkowitz

ABSTRACT

The Ethics Consultation Quality Assessment Tool (ECQAT) establishes standards by which the quality of ethics consultation records (ECRs) can be assessed. These standards relate to the ethics question, consultation-specific information, ethical analysis, and recommendations and/or conclusions, and result in a score associated with one of four levels of ethics consultation quality. For the ECQAT to be useful in assessing and improving the quality of healthcare ethics consultations, individuals who rate the quality of ECRs need to be able to reliably use the tool.

We developed a short course to train ethics consultants in using the ECQAT, and evaluated whether the participants (1) achieved an acceptable level of calibration in matching expert-established quality scores for a set of ethics consultations, and (2) were satisfied with the course. We recruited 28 ethics consultants to participate in a virtual, six-session course. At each session participants and faculty reviewed, rated, and discussed one to two ECRs. The participants' calibration in matching expert-established quality scores improved with repeated exposure at all levels of ethics consultation quality. Participants were generally more accurate when assessing consultation quality at the dichotomous level of "acceptable"

Robert Allan Pearlman, MD, MPH, is Chief of Ethics Evaluation at the VHA National Center for Ethics in Health Care and Professor at the University of Washington Schools of Medicine and Public Health Departments of Medicine, Health Services, and Bioethics and Humanities, Seattle, Washington. *Robert.Pearlman@va.gov*

David Alfandre, MD, MSPH, is Health Care Ethicist at the VHA National Center for Ethics in Health Care and Associate Professor at New York University School of Medicine Departments of Medicine and Population Health, New York, New York. *David.Alfrandre@va.gov*

Barbara L. Chanko, RN, MBA, is Health Care Ethicist at the VHA National Center for Ethics in Health Care and Affiliate Faculty at New York University School of Medicine Department of Population Health. *Barbara.Chanko@va.gov*

Mary Beth Foglia, RN, PhD, MA, is Health Care Ethicist at the VHA National Center for Ethics in Health Care and Affiliate Faculty at the University of Washington School of Medicine Department of Bioethics and Humanities. *MaryBeth.Foglia@va.gov*

Kenneth A. Berkowitz, MD, is Chief of Ethics Consultation at the VHA National Center for Ethics in Health Care and Associate Professor at New York University School of Medicine Departments of Medicine and Population Health. *Kenneth.Berkowitz@va.gov*

(scores of three or four) versus "unacceptable" (scores of one or two) than they were with a more specific score. Participants had higher rates of accuracy with the extreme ratings of "strong" (level four) or "poor" (level one). Although participants were highly satisfied with the course, only a minority of participants achieved the prespecified acceptable level of calibration (that is, 80 percent or greater accuracy between their score and expert-established scores). These results suggest that ECQAT training may require more sessions or need modification in the protocol to achieve higher reliability in scoring. Such trainings are an important next step in ensuring that the ECQAT is a tool that can be used to promote improvement in ethics consultation quality.

INTRODUCTION

Ethics consultation, sometimes referred to as healthcare ethics consultation, is a service provided by an individual or group in response to questions from patients, families, healthcare professionals, or other involved parties who seek to resolve uncertainty or conflict about value-laden concerns that emerge in healthcare.[1] Even though ethics consultations occur in most hospitals in the United States, there are few valid, reliable, and practical tools to evaluate, ensure, and improve the quality of ethics consultation.[2] The quality of ethics consultation is important because poor quality ethics consultation can cause harm or result in ethically inappropriate outcomes for patients and other stakeholders.[3]

The Ethics Consultation Quality Assessment Tool (ECQAT) establishes standards by which the quality of written healthcare ethics consultation records (ECRs) can be assessed.[4] Depending on the approach to charting ethics consultations in a healthcare institution, ECRs may include the patient's medical record alone or in combination with the ethics consultation service record. These standards pertain to the ethics question, consultation-specific information, ethical analysis, and recommendations and/or conclusions. Unlike other attempts at measuring quality, such as focusing on process steps (for example, elapsed time between a request and the response) or participants' satisfaction,[5] ECQAT assesses the quality of the written ethics consultation record. Further explication of the standards for judging quality and the rationale for relying on documentation through ethics consultation records have been discussed elsewhere.[6]

For the ECQAT to be useful in assessing the quality of the written records of the ethics consultations and informing quality improvement in ethics consultation, ratings of quality need to be reliable. Thus, raters need to be proficient in assigning rating scores such that they achieve a high degree of calibration. Calibration is the measure of raters' reliability in matching established quality scores as determined by experts for a set of ethics consultations, that is, the accuracy in scoring by raters. Achieving a high degree of calibration requires training and practice. Consequently, we developed a short course for training raters modeled after the U.S. Department of Agriculture (USDA) approach to training lawyers in holistically rating the quality of legal briefs.[7] The primary purpose of this article is to assess whether a short virtual training course is sufficient to achieve an acceptable level of calibration using the ECQAT. The secondary goal is to characterize the participants' experiences and perceived value of such a training course to inform future ECQAT training activities.

METHODS

Overview of the Ethics Consultation Quality Assessment Tool (ECQAT)

The ECQAT employs a holistic rubric assessment approach to the evaluation of the quality of ethics consultation that is based on the documentation in the consultation record. With holistic assessment, raters consider key elements and other factors that work together and score the narrative account on the "total impression" it makes upon the rater.[8] Because of the subjective aspects of a holistic approach to assessing quality, two raters are expected to rate each consultation record independently. If there are significant disagreements, these are discussed among the raters with the goal of achieving agreement.[9]

The ECQAT considers four key elements of ethics consultation records. (1) The first is the ethics question, which focuses the consultation process and response. After clarifying the ethical concern(s) that gave rise to the consultation request, the ethics question identifies whose values are uncertain or in conflict, and identifies the decision(s) or action(s) in question. (2) The second key element is the consultation-specific information that informs the ethical analysis. Consultation-specific information conveys (a) the most important information about the

medical and social facts, (b) the patient's and other involved parties' preferences, values, and interests, and (c) appropriate sources and processes that can be used to obtain relevant information. (3) The third key element, the ethical analysis, articulates and weighs valid and compelling arguments and counterarguments based on the consultation-specific information and ethics knowledge to provide justification for the conclusions and/or recommendations. Informing the analysis using ethics knowledge reflects the ethics consultants' expertise, that is, their familiarity with ethics "best thinking" and the application of it to the current case.[10] (4) The fourth key element is the conclusions and recommendations that promote ethical practices. This element should identify and explain the range of ethically justifiable options and clearly communicate practical recommendations that are ethically justifiable and responsive to the ethics question(s).

The overall ECQAT scoring of an ethics consultation ranges from one to four. Scores of one and two indicate less than acceptable quality. A score of one indicates "poor" quality because the ECR is significantly flawed, such that the conclusions/recommendations are not supportable. A score of two indicates "less than adequate" quality because the ECR is flawed in some ways that raise significant questions about whether the conclusions/recommendations are supportable. Scores of three and four indicate acceptable quality. A score of three indicates "adequate quality." The ECR may be flawed in some ways, but the flaws do not raise significant questions about whether the conclusions/recommendations are supportable. A score of four indicates "strong" ECR quality: minor flaws may exist, but the conclusions/recommendations are easily supportable, are based on appropriate information and ethics knowledge, and are responsive to the ethics question(s).[11] Examples of ECRs that were rated at each level of quality are available at *https://www.ethics.va.gov/activities/ecq.asp.*

Training

The training protocol was modeled after the USDA's approach to training lawyers in evaluating legal briefs.[12] Our protocol included a review of the principles of holistic rubric assessment, the key elements, and the scoring rubric, and an iterative review of the participants' group scores for each ECR with comparison to the expert rating, followed by group discussion about the rationale for the experts' rating. The expert ratings of an ECR's quality were determined through a deliberative and iterative process involving the ECQAT developers and feedback from Veterans Affairs (VA) and non-VA ethics consultants in the U.S. who were involved in the development of the ECQAT.[13] The ECRs used in the training course came from VA and non-VA sources and did not include information that identified institutions or patients. These established expert ratings included a narrative assessment that explained and justified the expert rating of each ECR.

The USDA experience also informed the number of sessions and the length of the course (six sessions over six days) and the virtual delivery of the training. In the first session (0.75 hours), the primary trainer (RAP) provided an overview of the ECQAT, instructions on the use of the tool, and an explanation of how an expert rating was established for a sample ECR by a consensus group of trained expert reviewers. Before all subsequent sessions, participants independently reviewed and rated two ECRs using the ECQAT and submitted their ratings to (RAP). During the second session (1.25 hours), the trainer led a discussion during which the participants explained the reasoning for their individual ratings. During the discussion, the trainer used the participants' explanations to reinforce the established scoring criteria. This second session was considered a practice session for gaining familiarity with the process and was not included in outcome measures for calibration (see below). In the third and following sessions, the trainer used the expert ratings and feedback developed for each ECR to reinforce the strengths and weaknesses of the ECR as well as the basis for the holistic score. Prior to third through sixth sessions, participants reviewed and rated two ECRs with narrative comments to support their rating. Prior to the discussions during these sessions, the participants were given the distribution of all of the participants' scores. In the third through sixth sessions (one hour per session), one or more of the co-authors joined the primary trainer and participants in their discussions about the reasoning for the established quality scores of the ECRs and the participants' ratings.

The virtual training occurred in July 2016. Initially the participants were divided into two

training groups. However, due to scheduling problems, some of the participants changed between groups to continue to participate in the training. After the initial review of the ECQAT and the rating of a sample ECR, the first discussion of consultation records (the practice session) involved ECRs with established quality a score of four (strong) and a score of two (less than adequate). The purpose of discussing an ECR scored at level four was to demonstrate a high quality ECR, and that high quality did not require perfection. The choice to discuss an ECR score at level two was to demonstrate an ECR assessed with less than acceptable quality. The sequencing of ECRs for the subsequent four training sessions used records with established quality scores of three and four, one and two, two and three, and one and four, assuring each level of quality was presented twice for participants' ratings. This sequence was determined by consensus amongst some of the authors (RAP, DA, BLC, KAB).

TABLE 1. Participants' characteristics (*N* = 28)

Characteristic	*n*	%
Work environment		
VA	22	79
Non-VA	6	21
Gender		
Female	19	68
Male	9	32
Leadership role in ethics consultation[1]	14	50
Primary profession[2]		
Social worker	5	23
Nurse	4	8
Physician	2	9
Administrator	2	9
Other (e.g., psychologist)	5	23
Ethics-related (e.g., clinical ethicist, director of ethics)	4	18
Education and training in clinical ethics[3]		
Formal, direct supervision by an experienced consultant	11	50
Educational resources and programs, such as seminars and workshops	10	45
Independent learning without formal, direct supervision	7	32
Completed a fellowship or graduate degree program in bioethics that included explicit training in ethics consultation	6	27
Completed a fellowship or graduate degree program in bioethics that did not include explicit training in ethics consultation	2	9

Characteristic	Yrs	Range
Median time conducting consultations (years)[4]	8	0-15

NOTES

1. Self-reported leadership role, such as chief, lead, chair, and Integrated Ethics® ethics consultation coordinator (VA).

2. Based on follow-up survey data from participants (*n* = 22).

3. Ibid. Respondents could select all that applied; thus, the percentages total more than 100%.

4. Based on follow-up survey data from participants (*n* = 22).

Recruitment

The request to participate in training sessions in the use of ECQAT was communicated to VA and non-VA audiences in May 2016 through the IntegratedEthics® listserv, a VA national listserv for ethics consultation coordinators at VA facilities, and the Medical College of Wisconsin (MCW) ethics listserv. The announcement for this convenience sample communicated that this training was for ethics consultants; that it would involve five assignments to be completed outside of the training (total time about five hours), and include six discussion sessions (total time about six hours); and that an important goal for this training was for participants to be able to use the ECQAT as a teaching tool at their facilities after the training to improve their own ethics consultations, and those of their ethics consultation services. After these announcements, 58 individuals expressed interest in participating in the ECQAT training course; 28 were available for the proposed dates and times of the sessions.

Outcome Measures

Calibration, or accuracy in scoring compared with expert-established quality scores for specific ECRs, was the primary outcome measure and was assessed two ways. First, we assessed the percent agreement with whether the score matched the dichotomous criteria; that is, less than acceptable ("below the bar," or a score of one or two) versus acceptable ("above the bar," or a score of three or four) rating. Second, we assessed the percent agreement with the more specific numerical score (that is, one to four). For the purposes of this pilot test training, the authors designated an 80 percent or higher level

of agreement as acceptable calibration for each of these approaches. This is less than the USDA standard (90 percent) for decisions pertaining to legal appeals, but was considered appropriate for this training because it was a first and untested experience offering the training course, and participants had a wide range of experience as ethics consultants. We compiled descriptive statistics (percentages) using Microsoft Excel (2016).

We also asked participants about their backgrounds (for example, training in ethics, healthcare role) and assessed their satisfaction with multiple aspects of the course through SurveyMonkey.[14] For example, we asked about whether the training objectives were met, and whether the trainer(s) seemed knowledgeable. We used a five-point Likert scale ranging from "strongly disagree" to "strongly agree." The questions are presented in table 3. We also asked the participants for their qualitative feedback on the course and recommendations for improving the learning experience. We used descriptive statistics provided through SurveyMonkey to present the results.

This pilot training was not reviewed by an institutional review board (IRB) as it was considered to represent a quality improvement project according to Veterans Health Administration (VHA) policy.

RESULTS

Participants' Characteristics

Of the 28 participants in the training, 18 had clinical backgrounds (64 percent) (see table 1). In response to the follow-up survey, 77 percent of the participants stated that they had a clinical background, and more than one-third reported having completed a fellowship program or received an advance degree in bioethics. Half of the survey respondents reported having received formal, direct supervision by an experienced member of a consultation service in performing ethics consultations. The median number of years conducting ethics consultations was eight. Two of the survey respondents reported zero years of experience conducting ethics consultations, but that they currently worked as members of an ethics committee or program.

Calibration

Over the course of the training, participants scored two ECRs at each numeric level of expert-established ECR quality. An acceptable calibration of 80 percent or greater occurred for "acceptable" versus "less than acceptable" ECR quality in the last three ECR assessments (84 percent, 100 percent, 100 percent; that is, aligned

TABLE 2. Levels of agreement in assessing ethics consultation quality between participants' ratings and established quality scores (*N* = 28)

Temporal sequence of ethics consultation records	Standardized score (pre-scored)	Agreement with "acceptable" or "less than acceptable"		Agreement with the numeric score	
		n	%	*n*	%
1	3	11	39	10	36
2	4	25	89*	20	71
3	1	18	66	9	31
4	2	8	28	3	10
5	2	10	36	10	36
6	3	24	84*	11	40
7	1	28	100*	18	65
8	4	28	100*	24	85*

NOTES

Temporal sequence of ethics consultation records indicates the sequencing of ethics consultation records after the two records that were used in the practice sessions. Numbers and percentages have been rounded to the nearest whole number. Scores of 1 and 2 indicate less than acceptable quality ethics consultation documentation. Scores of 3 and 4 indicate acceptable quality ethics consultation documentation.

* Acceptable calibration with percent agreement at 80% or greater

with the second exposure to ECR expert-established quality levels of three, one, and four, respectively). Acceptable calibration occurred for the exact numeric score only on the final session and only for an ECR expert-established quality score of four (see table 2).

Calibration improved with repeat exposure to ECRs at the same level of quality. When comparing first and second exposures to ECRs at the same overall level of quality (that is, "acceptable" versus "less than acceptable"), the range of improvement in calibration was 8 percent to 45 percent. When comparing first and second exposures to ECRs at the same numerical level of quality, the range of improvement in calibration was 4 percent to 34 percent. These results are presented in table 3.

Overall, there were three participants who achieved 100 percent accuracy between their scores and the expert-established quality scores in the last four ECRs at the expert-established quality levels of two, three, one, and four. All three had leadership roles in their ethics consultation services; two of the three worked outside the VA. There were seven participants who demonstrated 100 percent accuracy between their scores and the expert-established numeric quality scores in three of the last four ECRs. Five participants in this group had leadership roles with their ethics consultation services; four worked in the VA.

Participants' Satisfaction

Participants who responded to the follow-up survey reported they were highly satisfied with the ECQAT training experience (see table

TABLE 4. Participants' satisfaction with ECQAT training (*N* = 23)

	Questions	Scoring (Average)
1	The objectives of the training were clearly defined.	4.8
2	Participation and interaction were encouraged.	4.8
3	The content was organized and easy to follow.	4.3
4	The materials and handouts were helpful.	4.7
5	The training experience will be useful in my work.	4.7
6	The trainer was knowledgeable about the training topics.	5.0
7	The trainer was well prepared.	4.8
8	The training objectives were met.	4.4
9	I feel sufficiently trained to score an ethics consultation using the ECQAT.	3.8
10	The time allotted for the training was sufficient.	4.0
11	The technology used for the delivery of training was effective.	4.3
12	I would recommend this training to others.	4.7

NOTE
Follow-up survey with scoring: "strongly disagree" = 1, "disagree" = 2, "neutral" = 3, "agree" = 4; "strongly agree" = 5.

TABLE 3. Temporal tracking of levels of agreement in assessing ethics consultation quality between participants' ratings and established quality scores (*N* = 28)

Prescored ethics consultation record	First exposure (%)	Second exposure (%)	Percentage increase
Prescored ethics consultation record at quality level 1			
Agreement at the less than acceptable level*	66	100	34
Agreement with the numeric score 1	31	65	34
Prescored ethics consultation records at quality level 2			
Agreement at the less than acceptable level*	28	36	8
Agreement with the numeric score 2	10	36	26
Prescored ethics consultation record at quality level 3			
Agreement at the acceptable level*	39	84	45
Agreement with the numeric score 3	36	40	4
Prescored ethics consultation record at quality level 4			
Agreement at the acceptable level*	89	100	11
Agreement with the numeric score 4	71	85	14

NOTE
* "Less than acceptable" represents scores of 1 or 2; "acceptable" represents scores of 3 or 4.

4). This was expressed in their perceptions of the course's content, materials, and overall experience. Most strongly agreed with the statement "I would recommend this course to others." The lowest scoring evaluation element was whether participants felt sufficiently trained to independently score an ethics consultation record using the ECQAT. The average score for this item was 3.8 on a five-point scale (five = "strongly agree," four = "agree," three = "neutral," two = "disagree," one = "strongly disagree").

Qualitative Feedback

The qualitative comments were favorable and generally consistent with the objective satisfaction ratings. The participants expressed a desire for more training, such as an ongoing series of tutorials that would include an opportunity for feedback. Several participants suggested they wanted the opportunity to use the ECQAT to rate the quality of their own ECRs. Another suggestion was to have the training demonstrate multiple ECRs at the same level of quality before assessing ethics consultations at a different level of quality. One participant expressed an appreciation for the level of proficiency that would be required in the reliable application of ECQAT before becoming a rater of other consultants' ECRs at the participant's facility.

DISCUSSION

We report here on a pilot study that assessed whether a brief virtual ECQAT training was effective in achieving participants' calibration for assessing ECRs at varying levels of expert-established quality. This training, to our knowledge, is the first of its kind focusing on assessment of overall ethics consultation quality as reflected in ECR content, and included an educational overview of the ECQAT and repeated supervised practice with expert-established quality scored ECRs. Several findings from our pilot study are noteworthy. First, repeat exposure to ECRs at the same level of quality improved participants' calibration. Over the course of the training, the participants' accuracy improved with repeated exposure at every numeric level of ethics consultation quality and with the dichotomous rating of "less than acceptable" (that is, consults rated one or two) versus "acceptable" (that is, consults rated three or four). Second, participants were generally more accurate when assessing consultation quality at the level of "acceptable"/"unacceptable" than with the more specific numerical ratings. In addition, participants had higher rates of accuracy with the extreme ratings of "strong" quality (that is, four) or "poor" (that is, one) quality, but were less accurate with the intermediate quality scores of two and three. Third, ethics consultants in leadership roles seemed to achieve better calibration than other consultants toward the end of the pilot training. The reasons for this were not explored in this pilot training, but level of experience may be a factor.

However, despite these gains, a brief virtual training did not result in our prespecified acceptable level of calibration; only a minority of participants achieved 80 percent or greater accuracy between their score and expert-established quality scores. These results suggest that ECQAT calibration training may take longer than a six-session, short course for most participants to achieve accurate scoring, and that modifications of the training protocol may be necessary to achieve an acceptable level of calibration for individuals who want to use the ECQAT as a method to reliably assess and improve ethics consultation quality.

More experience is needed to better understand how best to train raters to reliably assess the quality of ethics consultations using ECQAT. Training protocols that modify the sequencing of ECRs can provide more empiric information about how well and quickly raters can achieve an acceptable level of calibration. Future efforts should also explore whether training outcomes (for example, an "acceptable" level of calibration) vary depending on the level and type of ethics and ethics consultation experience and training of the participant. Similarly, comparative effectiveness studies of different ECQAT calibration training protocols can help answer which protocols work best for different the strata of consultant (for example, level of training, extent of experience, leadership roles in ethics, academic versus non-academic settings, VA versus non-VA consultants).

Limitations to this pilot study exist. The study was conducted with a small, convenience sample of mainly VA employees and is not intended to be generalizable. However, the sample was appropriate for quality improvement and the purposes of this pilot project, including laying the groundwork for future efforts. Second,

the training did not include a training fidelity measure to assess the degree to which delivery of the training adhered to the training protocol. Although fidelity is an important part of evaluating the effectiveness of an intervention, we considered this training to be formative and wanted to be able to incorporate trainers' experience and participants' feedback to subsequent training sessions. Third, as argued elsewhere, ethics consultation documentation alone may not be an accurate reflection of some aspects of the quality of an ethics consultation.[15] This is a valid concern, especially when it regards interpersonal processes such as clear and thoughtful communication, attentive listening, and expressions of empathy. However, documentation in the health record is still considered the industry standard for demonstrating what occurs in a medical encounter and the rationale (that is, reasoning) for recommendations.[16]

The lack of calibration to the prespecified acceptable level of calibration and the need for further development of the ECQAT training protocol does not preclude the use of the ECQAT for training and educational purposes. For instance, the ECQAT can be used to promote discussion and education about the quality of ethics consultations with ethics consultants and ethics committee team members. ECQAT-based discussion among raters of the same ECR can promote mutual understanding of raters' opinions and perspectives on the quality of an ECR. Ethics consultants or services can apply the ECQAT as a "quality check" to assess whether their consultations include the key elements required in quality consultations. Finally, experienced consultants can use ECQAT for coaching sessions with individuals or teams.

CONCLUSION

The ECQAT establishes standards by which the quality of ECRs can be assessed. For this tool to be practical, reliable, and useful, ECQAT raters should have a high degree of calibration with expert-established quality scores. Trainings designed to enhance calibration are an important next step in ensuring that the quality of ethics consultations continues to improve.

DISCLAIMER

The contents reflect the view of the authors and do not represent the views of the United States Department of Veterans Affairs, the United States government, New York University School of Medicine, or the University of Washington School of Medicine.

NOTES

1. American Society for Bioethics and Humanities (ASBH), *Core Competencies for Healthcare Ethics Consultation*, 2nd ed. (Glenview, Ill.: ASBH, 2011).

2. N. Dubler et al., "Charting the Future: Credentialing, Privileging, Quality, and Evaluation in Clinical Ethics Consultation," *Hastings Center Report* 39, no. 6 (November-December 2009): 23-33; A. Favia et al., "A Model for the Assessment of Medical Students' Competency in Medical Ethics," *American Journal of Bioethics Primary Research* 4, no. 4 (October-December 2013): 68-83; M. Svantesson et al., "Outcomes of Moral Case Deliberation—The Development of an Evaluation Instrument for Clinical Ethics Support (the Euro-MCD)," *BMC Medical Ethics* 15, no. 1 (8 April 2014): 30; S.E. Bliss et al., "Measuring Quality in Ethics Consultation," *The Journal of Clinical Ethics* 27, no. 2 (Summer 2016): 163-75; K. Wasson et al., "Developing an Evaluation Tool for Assessing Clinical Ethics Consultation Skills in Simulation Based Education: The ACES Project," *HEC Forum* 28, no. 2 (2016): 103-13.

3. R.A Pearlman et al., "Ethics Quality Assessment Tool: A Novel Method for Assessing the Quality of Ethics Case Consultations Based on the Written Records," *American Journal of Bioethics* 16, no. 3 (March 2016): 3-14.

4. Ibid.

5. Dubler et al., "Charting the Future," see note 2 above; K.A. Bramstedt et al., "Optimising the Documentation Practices of an Ethics Consultation Service," *Journal of Medical Ethics* 35, no. 1 (January 2009): 47-50; M. Repenshek, "Attempting to Establish Standards in Ethics Consultation for Catholic Health Care: Moving Beyond a Beta Group," *Health Care Ethics USA* 18, no. 1 (Winter 2010): 5-14; M. Repenshek, "Continuous Quality Improvement Initiatives in Ethics: A Proposed Communication Tool," *Health Care Ethics USA* 20, no. 4 (Fall 2012): 2-12; Svantesson et al., "Outcomes of Moral Case Deliberation," see note 2 above.

6. Pearlman et al., "Ethics Quality Assessment Tool," see note 3 above.

7. R. Klurfeld and S. Placek, "Rhetorical Judgments: Using Holistic Assessment to Improve the Quality of Administrative Decisions," *Journal of the National Association of Administrative Law Judiciary* 31, no. 2 (15 October 2011): 526-54.

8. Klurfeld and Placek, "Rhetorical Judgments," see note 7 above; R. Cherry and P. Meyer, "Reliability Issues in Holistic Assessment," in *Validating Holistic Scoring for Writing Assessment: Theoretical and Empirical Foundations,* ed. M. Williamson and B. Huot (Cresskill, N.J.: Hampton Press, 1993), 109-41; L. Beyreli and G. Ari, "The Use of Analytic Rubric in the Assessment of Writing Performance—Inter-rater

Concordance Study," *Educational Sciences: Theory and Practice* 9 (2009): 105-25.

9. Klurfeld and Placek, "Rhetorical Judgments," see note 8 above.

10. K.A. Berkowitz et al., *Ethics Consultation: Responding to Ethics Questions in Health Care,* 2nd ed. (Washington, D.C.: Department of Veterans Affairs, 2015), *https://www.ethics.va.gov/docs/integrated ethics/ec_primer_2nd_ed_080515.pdf*

11. For a more complete description of ECQAT, see Pearlman et al., "Ethics Quality Assessment Tool," see note 3 above.

12. Klurfeld and Placek, "Rhetorical Judgments," see note 8 above.

13. Pearlman et al., "Ethics Quality Assessment Tool," see note 3 above.

14. SurveyMonkey, Advantage Plan, Survey Monkey, Inc., San Mateo, Calif., 2018, *www.surveymonkey.com*.

15. C.R. Bruce and T.M. Bibler, "Not There Yet: Evaluating Clinical Ethics Consultation in an Accountability Culture," *American Journal of Bioethics* 16, no. 3 (2016): 46-8; B. Molewijk et al., "What Quality Is Actually Assessed Within Written Records?" *American Journal of Bioethics* 16, no. 3 (March 2016): 48-50.

16. A. Donabedian, "The Quality of Care: How Can It Be Assessed?" *Journal of the American Medical Association* 260, no. 12 (1988):1743-8.

Technical Considerations for Implementation of Tele-Ethics Consultation in the Intensive Care Unit

Laura S. Johnson, David M. Brennan, and Nneka O. Sederstrom

ABSTRACT

Background

Robust ethics consultation services cannot be sustained by all hospitals; consultative service from a high-volume center via teleconferencing is an attractive alternative. This pilot study was conceived to explore the feasibility and understand the practical implications of offering such a service.

Methods

High-definition videoconferencing was used to provide real-time interaction between the rounding clinicians and a remote clinical ethicist. Data collection included: (1) evaluation of the hardware and software required for teleconferencing, and (2) comparison of ethics trigger counts between the remote and on-site ethicist during rounds.

Results

Issues with audio represented the majority of technical problems. Once technical difficulties were addressed, the on-site ethicist's count of "triggers" was not statistically different from the count of the remote ethicist.

Conclusion

Remote clinical ethics rounding is feasible when the equipment is optimized. Remote ethicists can identify similar numbers of "triggers" for possible ethical issues when compared to on-site ethicist numbers.

Laura S. Johnson, MD, FACS, is Assistant Professor of Surgery, Georgetown University School of Medicine, and an Attending Surgeon in the Section of Burns and Trauma at Medstar Washington Hospital Center in Washington, D.C. *Laura.S.Johnson @medstar.net*

David M. Brennan, MBE, is Director of Telehealth Initiatives at MedStar Institute for Innovation in Washington, D.C. *David.M.Brennan@medstar.net*

Nneka O. Sederstrom, PhD, is Director of Clinical Ethics at the Children's Minnesota Center for Bioethics in Minneapolis, Minnesota. *Nneka. Sederstrom@childrensmn.org*

INTRODUCTION

With ever-increasing ease of use and access to technology evident in daily life, enthusiasm for applying new technologies to fundamental problems in medicine has likewise increased. Lack of access to physicians and other healthcare providers is one such critical problem that impacts patients around the world.[1] Telemedicine has been examined as a solution in medical fields ranging from burn surgery to psychiatry, and healthcare fields that parallel medicine (such as pharmacy), with positive results.[2] How-

ever, to date, no one has looked at the utility of using videoconferencing to provide remote ethics consultation and rounding services to hospitals that do not have an ethics team available around the clock. While the Joint Commission mandated an inhospital mechanism for addressing ethical issues in all hospitals in the United States in 1994,[3] the nature and type of that mechanism was left purposely vague to allow hospitals flexibility in meeting the requirement. However, fully mature ethics consultation and rounding services are not common across the U.S., leaving many programs at a disadvantage in addressing problems beyond those identified as critical.

In order to provide year-round ethics consultation and rounding services in the critical care setting to a wide variety of hospitals and medical groups, many of whom may only have a limited need over the course of an academic year, a tele-ethics service line could be of tremendous value. However, the feasibility of such a service depends on technical and human factors, both of which need to be investigated in a small, well-controlled environment.

MATERIALS AND METHODS

This pilot study was conceived and conducted within the medical and surgical intensive care units (ICUs) of a large, urban medical center after approval by its institutional review board as a quality improvement project. Standard of practice at this institution is weekly participation in ICU rounds by a member of the ethics consultation service, during which time he or she directly interacts with attendings, residents, medical students, nurses, and associated healthcare providers on-site. The Center for Ethics at Medstar Washington Hospital Center, established in 1982, is a mature clinical ethics program that is fully integrated within the hospital and sees a large, diverse number of consultations during an academic year (300 to 400). The center is staffed by a medical director, three full-time clinical ethicists, and a clinical ethics educator, totaling approximately 70 years of clinical ethics experience.[4]

While the same ethicist would be present for multiple patient evaluations during a given session, ethicists were purposely rotated throughout this study. The rotation included sessions conducted between remote and on-site ICUs and between the ethicists' "home" ICUs and other ICUs over multiple sessions. The architectural design of all of the ICUs in which this service was tested is the same, resulting in the same technical challenges across the units. During rounds, the rounding ICU attending joined the virtual ethics consults, and a video feed of the remote ethicist appeared on a workstation on wheels (WoW). On-site ethicists assumed their usual position in the group of physicians, resident physicians, and allied careproviders present on rounds.

To facilitate the participation of the remote ethicists, videoconferencing capability was added to the existing mobile computer units that are used during rounding on the ICUs. Mirroring what the authors expect to occur at medical centers with their own information technology departments, a videoconferencing software platform that was already in use within the system was used. Each of these WoWs was equipped with videoconferencing software as well as a USB (universal serial bus) camera and echo-cancelling speaker/microphone. Equivalent software and hardware were installed in the ethics office for use by the remote ethicists. The system provided a HIPAA-compliant (Health Insurance Portability and Accountability Act of 1996) platform for real-time high-definition videoconferencing. A link to a virtual ethics consult videoconference "room" was placed on the desktops of the WoWs and of the remote ethicists' computers. This room was accessible via a six-digit PIN (personal identification number) access code and allowed participants to see and hear each other and view and discuss patients and patients' information securely. No financial support was provided to this initiative by either the hardware or the software manufacturers.

Two types of data were collected during this phase of the project: technical data and consultant-specific data. The technical data encompassed a list of the technical problems encountered with the implementation of real-time videoconferencing, and included issues of system connectivity, device utilization, and audiovisual problems. Consultant-specific data were collected to identify any potential differences between remote and on-site ethicists' rounding evaluations of clinical ethics issues with patients. Verbal and nonverbal cues ("triggers") are major sources of information for rounding clinical ethicists because they indicate possible ethical dilemmas among team members. Nonverbal cues can include everything from changes

in facial expression, shifts in position or other movement by staff during presentations, to removal of self from rounding. The static focus of the video camera raised concerns that such cues could go unnoticed. Notes made by the tele-ethics consultants regarding the potential need for consultations, educational topics, and pending problems were compared to lists of the same issues gathered by a standard weekly rounding ethicist (see table 1). "Ethics consultation triggers identified" were a marker to evaluate the ability of tele-ethics consultation to identify subtle cues that were often the first signs of an ethical conflict.

TABLE 1. The standard ethics consultation "triggers" list

Patient's wishes are unclear
Patient refuses treatment
Capacity
Noncompliance with treatment
Interfamily disagreement relatives/surrogates/caregivers
End of life
Advance directives
Power of attorney for healthcare
Allow natural death order
Withdraw/withhold treatment
Life-sustaining treatment versus comfort care
Need for clarification of the goals of care
Ethical concerns about the appropriateness of current treatment
Confidentiality/disclosure
Resource management considerations
Financial systems problems
Fairness/justice
Allocation/utilization
Communication
Poor communication across providers
Poor communication between patient/family/providers
Poor communication amongst family members
Disruptive family
Increased decision making complexity
Frequent admissions
Involvement of life-sustaining technologies
Multiple comorbidities
Single system problem
Disruptive/threatening patient/family behavior
Resource allocation/utilization
Power imbalance between/among providers
Unresolved pain (as a potential marker of unaddressed issues)
Unclear surrogate

The study was designed to evaluate the feasibility of the initiative and to identify the technical and human factors of using videoconferencing to facilitate participation in remote ethics consultation. A noninferiority design was used to compare the ability of on-site ethicists and remote ethicists to identify triggers for possible ethical issues during ICU rounding. A noninferiority design potentially increases the number of available interventions for a particular problem if a new intervention is deemed to be equivalent to a current intervention. A Poisson distribution analysis, used to assess the true incidence of uncommon events in populations, was used to evaluate the difference in counts on these lists of ethical issues identified by the differently located ethicists.

RESULTS

A total of seven separate rounding days were performed with 30 separate patient encounters evaluated in three separate ICUs. The ICU populations encompassed a broad range of medical and surgical patients, although the ICU teams rounded separately, depending on whether a patient was admitted to the medical ICU or to one of two surgical ICUs. It is worth noting that patient-centered rounds were not mandated in any of the units during the time of this study; the presence of patients' family members was variable as a result.

Technical Evaluation

Following a brief tutorial at the initiation of the study, both the rounding team and the remote ethicists judged the videoconferencing platform to be simple to use. The hardware setup on both the WoW and the computer in the ethics office was straightforward and consistent with modern "plug and play" electronics. However, the placement of the camera/speaker on the WoW was modified several times over the seven days to improve visibility and audio quality. The original configuration can be seen in figure 1. It was noted very quickly that the field of view provided by the webcam was rather limited and that a camera with a wider viewing angle or pan/tilt capabilities would be helpful to better evaluate group dynamics. Audio function was somewhat more difficult to optimize due to the high degree of ambient noise in the ICUs, most often from ICU alarms (ventilators/

cardiac monitors/intravenous pumps), and the conversations of unit staffs. A total of 14 of the 30 patient encounters were judged to be "inaudible" by the remote ethicists.

Both of these issues were addressed simultaneously after two sessions through the use of a telescoping arm that extended up from the top of the WoW (see figure 2). This modification helped to better orient the speaker/microphone and camera toward the "circle" of the rounding team. It resulted in improved audio quality and the ability to more accurately hear more of the clinical staff. Also, positioning the camera to capture more of a "birds-eye" view helped to minimize the number of obstructions to the view of the remote ethicists.

Consultant Evaluation

Each of the 30 patient encounters involved a remote ethicist and an on-site ethicist. Remote sessions were performed by each clinical ethicist at least twice, with one of the other two ethicists on-site in the ICUs; 14 of the encounters were judged "inaudible" by the remote ethicists; the majority of those were in the first two sessions and were remedied by equipment adjustments. The remaining 16 encounters occurred with six surgical ICU patients and 10 medical ICU patients. Overall, the inperson ethicists observed more triggers than the remote ethicists did. However, comparing trigger counts for all patient encounters in which there were no audio difficulties, the on-site ethicists' counts fell within the 99 percent Poisson confidence interval of the remote ethicists' counts, indicating no significant difference (68 versus 53). (See figure 3.)

DISCUSSION

The integration of technology and medicine in the modern age has resulted in advances ranging from face transplantation to exoskeletons for paraplegics. And yet, the need to deliver ethically appropriate and sensitive care continues to be a challenge for healthcare practitioners.[5] Often, a voice from outside the medical team can provide the necessary perspective on difficult choices about patients and their potential treatment pathways.[6] Equally relevant in an era of cost-conscious provisioning of care, early ethics intervention has been suggested to decrease patients' length of stay and resource utilization.[7] But not all hospitals can afford to maintain clinical ethics consultation services, and not all services have the same breath and depth of experience. A brief review of the existing literature indicates that the volume of cases for ethics consultation services ranges from eight to 500 cases per year.[8] Both patients and physicians could benefit from a way to access a robust clinical ethics consultation service that is not necessarily available at their home institution. Tele-ethics consultation and rounding are increasingly feasible solutions to this problem. As electronic medical records become more prevalent and wireless devices deliver information seamlessly, the infrastructure to support secure telecommunication regarding patients' care is increasingly accessible to healthcare practitioners at the bedside.[9]

We begin to evaluate the necessary components of a tele-ethics rounding service with this pilot study. Noise is an ongoing source of stimulus in ICUs, and recent data report noise levels that are con-

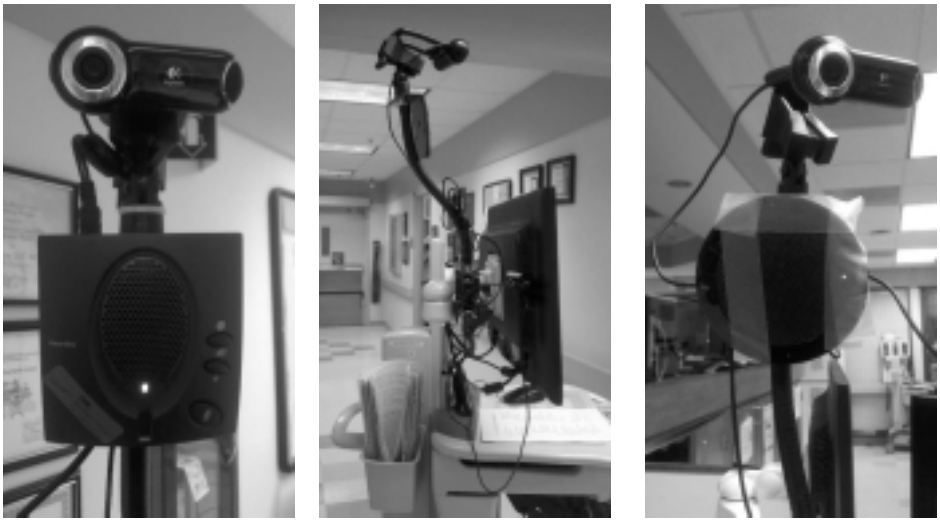

FIGURE 1. Initial workstation configuration, showing limited field of view for remote ethicist. Photographs by L.S. Johnson, MD. Used with permission.

sistently above U.S. Environmental Protection Agency standards.[10] It is not surprising that noise was the most significant detriment to a successful remote ethics rounding. However, once noise is better controlled, remote ethics consultants can identify enough audio and visual triggers to suggest that ethical issues might need to be addressed. Even one cue can be enough to trigger a more involved discussion that ultimately can shed light on a wide variety of ethics-related topics.

There are several limitations to this study. As it was a feasibility study, only a limited number of sessions were observed; this prevented a detailed analysis of the type and quality of triggers identified, including whether or not some triggers were impossible to identify via tele-ethics consultation. Further work will address these issues. The lack of 360-degree visualization of the team was raised as a potential problem. However, even on-site consultants do not have eyes in the back of the head; when team members want to avoid discussing a problem, they can usually do so. It is conceivable that "off-camera time" by staff would itself cue remote ethicists to problems that need group discussion. Ultimately, familiarity between the regular members of a medical team and ethics consultants does allow for more inferences to be drawn, even via remote consultation, than perhaps a consultant who is unfamiliar with a team might be able to make.

This study looked primarily at technical feasibility. To gain a greater sense of the impact and

FIGURE 2. Revised workstation configuration, showing improved field of view for remote ethicist. Photographs by L.S. Johnson, MD. Used with permission.

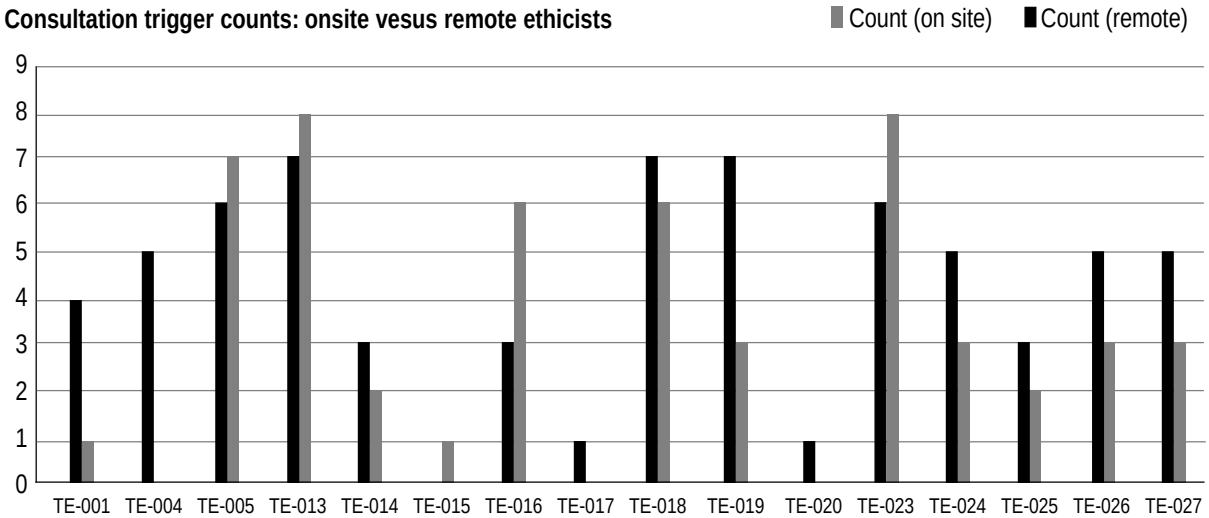

FIGURE 3.

potential for the participation of remote ethicists to meet a growing clinical need, a follow-up study is currently underway that explores the ability of a remote ethics consultant to render more than just a technical decision. Participation in meaningful, authentic interactions with staff allows ongoing learning and growth from the discussion; preliminary assessments seem to suggest positive interactions with resident physicians and ancillary staff are possible.

CONCLUSIONS

It is feasible to have remote clinical ethics rounding as long as the equipment used is optimized to maximize audio and video quality. Remote ethicists appear to be able to identify triggers for possible ethical issues in similar numbers to on-site ethicists, likely sufficient to prompt further appropriate in-depth discussions. Having access to a mature clinical ethics department with remote consultation and rounding abilities will be beneficial to improving care for patients in the ICU setting and for assisting clinical staff in making good clinical judgments.

ACKNOWLEDGMENTS

The authors would like to acknowledge the ethicists of the Center for Ethics at Medstar Washington Hospital, the Medstar Institute for Innovation, and the intensivists of the Sections of Medical and Surgical Critical Care for their participation with this study.

NOTES

1. G.F. Sheldon et al., "The global health workforce shortage: role of surgeons and other providers," *Advances in Surgery* 42 (2008): 63-85.

2. D.L. Wallace et al., "A systematic review of the evidence for telemedicine in burn care: with a UK perspective," *Burns* 38, no. 4 (2012): 465-80.

3. P. Yam et al., "Implementation of an antimicrobial stewardship program in a rural hospital," *American Journal of Health-System Pharmacy* 69, no. 13 (2012): 1142-48; J. Chipps, P. Brysiewicz, and M. Mars, "Effectiveness and feasibility of telepsychiatry in resource constrained environments?" *African Journal of Psychiatry* 15, no. 4 (2012): 235-43; Joint Commission on Accreditation of Healthcare Organizations, "Management of the Environment of Care," *Joint Commission Perspectives* 17, no. 1 (January-February 1997): EC7-9.

4. Based on the experience of the third author, Nneka O. Sederstrom, former Director of the Center for Ethics at MedStar Medical Center.

5. J.M. Breslin et al., "Top 10 health care ethics challenges facing the public: Views of Toronto bioethicists," *BMC Medical Ethics* 6 (2005): 6:E5; B.T. Thompson et al., "Executive Summary: Challenges in end-of-life care in the ICU: Statement of the 5th International Consensus Conference in Critical Care, Brussels, Belgium, April 2003," *Critical Care Medicine* 32, no. 8 (2004): 1781-4; J. Carlet et al., "Challenges in end-of-life care in the ICU: Statement of the 5th International Consensus Conference in Critical Care: Brussels, Belgium, April 2003," *Intensive Care Medicine* 30, no. 5 (2004): 770-84; L. Flannery, L.M. Ramjan, and K. Peters," End-of-life decisions in the Intensive Care Unit (ICU)—Exploring the experiences of ICU nurses and doctor—A critical literature review," Australian Critical Care 29, no. 2 (2015): 97-103.

6. E.G. DeRenzo, N. Mokwunye, and J.J. Lynch, "Rounding: How everyday ethics can invigorate a hospital's ethics committee," *HEC Forum* 18, no. 4 (2006): 319-31.

7. L.S. Johnson, J. Lesandrini, and G.S. Rozycki, "Use of the medical Ethics Consultation Service in a busy Level I trauma center: Impact on decision-making and patient care," *American Surgeon* 78, no. 7 (2012): 735-40; L.J. Schneiderman et al., "Effect of ethics consultations on nonbeneficial life-sustaining treatments in the intensive care setting: A randomized controlled trial," *Journal of the American Medical Association* 290, no. 9 (2003): 1166-72.

8. B. Spielman et al., "Case Complexity and Quality Attestation for Clinical Ethics Consultants," *The Journal of Clinical Ethics* 26, no. 3 (Fall 2015): 231-40; E.B. Tapper et al., Ethics consultation at a large urban public teaching hospital," *Mayo Clinical Proceedings* 85, no. 5 (2010): 433-8; J.R. Moeller et al., "Functions and outcomes of a clinical medical ethics committee: A review of 100 consults," *HEC Forum* 24, no. 2 (2012): 99-114; M.E. Romano et al., "Mandatory ethics consultation policy," *Mayo Clinical Proceedings* 84, no. 7 (2009): 581-5.

9. American Telemedicine Association, *Telemedicine Frequently Asked Questions,* 2012, *www.americantelemedicine/telemedicine-faqs.*

10. C.R. Tainter et al., "Noise Levels in Surgical ICUs Are Consistently Above Recommended Standards," *Critical Care Medicine* 44, no. 1 (2016): 147-52.

Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations

Jennifer E. deSante-Bertkau, Michelle L. McGowan, and Armand H. Matheny Antommaria

ABSTRACT

Introduction

Classifying the ethical issues in clinical ethics consultations is important to clinical practice and scholarship. We conducted a systematic review to characterize the typologies used to analyze clinical ethics consultations.

Methods

We identified empirical studies of clinical ethics consultation that reported types of ethical issues using PubMed. We screened these articles based on their titles and abstracts, and then by a review of their full text. We extracted study characteristics and typologies and coded the typologies.

Results

We reviewed 428 articles; 30 of the articles fulfilled our inclusion criteria. We identified 27 unique typologies. Each typology contained five to 47 categories (mean = 18). The most common categories were do-not-attempt-resuscitation orders (19 typologies, 70 percent), capacity (18 typologies, 67 percent), withholding (18 typologies, 67 percent), withdrawing (17 typologies, 63 percent), and surrogate or proxy (16 typologies, 59 percent). Only seven (26 percent) of the typologies contained all five of the most common categories.

The typologies we used to characterize clinical ethics consultations exhibit significant heterogeneity and several conceptual limitations. A common typology is needed whose development may require multi-institutional collaboration and could be facilitated by professional organizations.

Jennifer E. deSante-Bertkau, MD, MBE, is an Assistant Professor in the Ethics Center and Division of Hospital Medicine, Cincinnati Children's Hospital Medical Center and the Department of Pediatrics at the University of Cincinnati College of Medicine in Cincinnati, Ohio. *Jennifer.desante@cchmc.org*

Michelle L. McGowan, PhD, is a Research Associate Professor in the Ethics Center and Division of General and Community Pediatrics, Cincinnati Children's Hospital Medical Center, the Department of Pediatrics at the University of Cincinnati College of Medicine, and the Department of Women's, Gender, and Sexuality Studies at the University of Cincinnati College of Arts & Sciences.

Armand H. Matheny Antommaria, MD, PhD, is a Professor and Director of the Ethics Center at Cincinnati Children's Hospital Medical Center and Professor in the Department of Pediatrics at the University of Cincinnati College of Medicine.

INTRODUCTION

Hospital ethics committees and clinical ethics consultation proliferated between 1983 and 2007. One survey published in 1983 found that approximately 1 percent of all hospitals in the United States had ethics committees that could become involved in decisions regarding individual patients.[1] By 2007, 81 percent of general hospitals and 100 percent of hospitals with more than 400 beds had established ethics consultation services.[2] During this time, there was substantial discussion of the goals of consultations, the competencies of consultants, and the evaluation of consultation processes.[3] Observational studies described the process of consultation including the frequency of consultation requests, the characteristics of requestors and patients, and the types of ethical issues encountered. Some studies examined potential associations between consultation and mortality and/or length of stay, and/or reported the satisfaction of requestors. Few intervention trials, however, have been conducted, and trials that have been conducted show variable results.[4]

Observational studies of consultations have a variety of potential benefits. Studies of individual institutions can be used to evaluate trends in consultation requests, plan educational programs, identify systems issues, and evaluate changes in response to interventions. They may provide data that can be used to justify institutional support for clinical ethics consultation services. Comparisons between institutions also may be beneficial. Such comparisons allow descriptions of variation between different types of institutions, including those associated with different clinical ethics consultation methods.

A typical example of an observational study is Johnson, Church, Metzger, and Baker's analysis of ethics consultations conducted at St. Jude Children's Research Hospital from 2000 to 2011.[5] St. Jude is a 78-bed pediatric hospital that specializes in the treatment of children with cancer, human immunodeficiency virus infection, blood disorders, and primary immunodeficiencies. The authors reported descriptive demographic data, the primary reason for consult requests, outcomes, and involvement with external services, for example, palliative care and child protective services. They compared their results with other recently published studies.

Several commentators have identified methodological issues regarding this type of study. Antommaria argued for the need for a common list of reasons to advance scholarship on clinical ethics consultation[6] and Henriksen Hellyer and colleagues argued that "one of the most challenging aspects of interpreting ethics consultation practices across settings . . . is a nonstandard classification of consult types or 'reason for consult.' "[7] Gilliam, McDougall, and Delany proposed their own alternative typology of categories.[8] Given the debate over the appropriate development and content of consultation typologies, we conducted a systematic review of the literature to describe the typologies used to characterize clinical ethics consultations.

METHODS

Systematic Review

Inclusion criteria for the systematic review were (1) empirical studies of clinical ethics consultation that (2) categorized the ethical issues that prompted or were identified in the consultation, and (3) provided data on the number of consultations performed. Studies of the ethical issues encountered by healthcare professionals, causes of moral distress, and ethical issues in research were excluded. Articles that described each individual consultation, but did not categorize them, and articles that described selected consultations were also excluded. A search strategy was developed with the assistance of two medical librarians (Alison Kissling and Martina Darragh). It included indexed terms and text words to capture concepts related to empirical studies, clinical ethics consultation, and categories or types. (The full search strategy is available from the corresponding author.) The search was limited to the U.S. National Library of Medicine's PubMed, as this database indexes the journals most likely to publish such studies. The search was limited to articles published in English since 1980. Our review was registered with the international prospective registry of systematic reviews, PROSPERO.[9]

Two of the authors (JdB and AHMA) independently screened the titles and abstracts of the articles, and then independently reviewed the full text of the articles. The authors identified additional articles from the references and independently reviewed the full text of those articles. Articles that either author believed might be relevant based on review of the title and abstract or the references advanced to re-

view of the full text and disagreements following review of the full text were resolved by consensus.

Data Extraction and Coding

Two of the authors (JdB and AHMA) extracted the name of the institution from the articles that were included in the study, as well as the type of institution, the study population, the data collection period, the number of consultations, the primary outcome measure used, and the method used to derive the typology. These two authors characterized the primary outcome measure used in each article as either the reason(s) for consultation or the ethical issue(s) identified during the process of the consultation.

These authors characterized the primary outcome measure in the selected articles by whether the measure was identified prospectively or retrospectively, and whether the measure was defined by the requestor of the consultation, the ethics consultant, or the author(s) of the article. For each article, the authors categorized the method used to derive the typology as deductive, inductive, or both. By *deductive,* the authors mean that the typology used in each article was based on *a priori* categories or a review of the literature, and by *inductive,* the authors mean that the typology used emerged from a review of the consultations. Typologies were extracted from the articles by one of the authors (JdB) and reviewed for accuracy by another individual (Jennifer Longbottom). Some articles presented multiple typologies, for example, typologies of "primary consult activity" and "organizational issues," but only one typology of ethical issues was extracted per article.[10] Disagreements regarding the assignment of typology were resolved by consensus between the authors.

Using inductive and deductive reasoning, the authors developed a coding scheme that would allow comparison across studies.[11] Some codes were narrowly defined based on their common use in the ethics literature, for example, "best interest." Other codes were created to combine categories from different studies that were felt to represent similar ethical issues. For example, "durable powers of attorney for healthcare" and "living wills" were included in the code "advanced care planning." Some codes were gathered into clusters based on their relation to each other. For instance, the distinct codes for the different types of interpersonal conflict were combined into a cluster, or grouping that we called "conflict." The typologies were not exhaustively coded to the level of codes that only appeared a small number of times. For example, "community considerations,"[12] "guns in the home of home care patients,"[13] and "initiation of an individual attempt to cure"[14] each appeared in only one typology and were not coded. The resulting code schema was then utilized for thematic analysis of the typologies.

After reviewing the initial subsets of the typologies to refine the codes and coding rules, the authors reviewed and discussed how to apply the codes to enhance intercoder reliability.[15] The typologies were independently coded by all three of the authors using ATLAS.ti 8.0 qualitative software. Any discrepancies were discussed and resolved by consensus.

Figure 1. Data extraction process

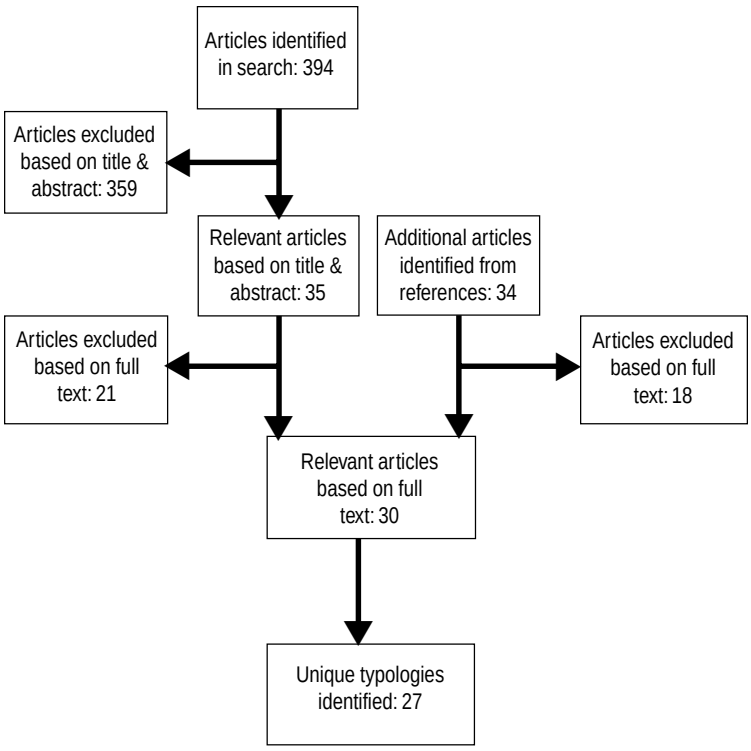

TABLE 1. Characteristics of studies

Article authors	Institution	Institution type	Study population	Data collection period	Duration of data collection (months)	Number of consultations	Total number of reasons or issues	Primary outcome measure	Derivation of typology	Number of categories
Boissy, Ford, Edgell, and Furlan	Cleveland Clinic, Cleveland, Ohio	Academic	Neurology inpatient, neurology step down, neuro-intensive care units. Nonneurological diagnoses excluded	1998-2004	72	49	49	Reasons for consultation identified by authors	Inductive	20
Bruce, Smith, Hizlan, and Sharp	Cleveland Clinic Cleveland, Ohio	Academic	--	Jan. 2007-Dec. 2008	24	478	NS	Ethical issues identified retrospectively by consultant	--	8
Forde and Vandvik	National Hospital Oslo, Norway	Academic	--	1996-2002	72	31	100	Reasons for consultation identified retrospectively by consultant	--	13
Fukuyama, Asai, Itai, and Bito	Clinical Ethics Support and Education Project, Japan[1]	--	--	Oct. 2006-Dec. 2007	15	25	25	"Consultation request classification" identified prospectively by consultant	--	13
Henriksen Hellyer et al.	Mayo Clinic, Rochester, Minn.	Academic	< 18 years old, or ≥ 18 years old, never competent, and treated in pediatrics	May 1995-June 2014	241	64	64	Reason for consultation identified retrospectively by consultant	Deductive	47
Johnson, Church, Metzger, and Baker	St. Jude's Children's Research Hospital, Memphis, Tenn.	Children's specialty	--	May 2000-Dec. 2011	140	53	79	Ethical issues identified retrospectively by authors	Both	27
Johnson, Lesandrini, and Rozycki	Grady Memorial Hospital, Atlanta, Ga.	Academic	Trauma patients	Jan. 2000-Dec. 2010	132	108	108	Ethical issues identified retrospectively by consultants	Deductive, based on Fox, Myers, and Pearlman[5]	28
La Puma (1987)	University of Chicago Hospitals	Academic	--	July 1985-June 1986	12	27	27	Ethical issues identified retrospectively by consultants	--	14
La Puma et al. (1988)	University of Chicago Hospitals and Clinics	Academic	--	July 1986-June 1987	12	51	138[6]	Reasons for consultation identified prospectively by requestor and consultant	Inductive	13
La Puma, Stocking, Darling, and Siegler	Lutheran General Hospital, Park Ridge, Ill.	Community	--	Jan. 1988-Dec. 1989	24	104	313[7]	Reason for consultation identified by requestor and consultant	--	18

McDougall and Notini	Royal Children's Hospital, Melbourne Vic., Australia	Children's	--	May 2005-Dec. 2014	116	184	184	Reason for consultation identified by requestor and consultant	Both	9
Moeller et al.	Akron City Hospital Akron, Ohio	Community	--	July 1997-March 2009	152	100	195	Reason for consultation identified retrospectively	--	9
Nilson, Acres, Tamerin, and Fins	New York-Presbyterian Healthcare System[2]	Healthcare system	--	2002 (30 days)	1	53	79	Reasons for consultation identified retrospectively by consultant	Both	9
Opel et al.	Seattle Children's Hospital, Seattle, Wash.	Children's	--	1996-2006	132	71	71	Reason for consultation identified retrospectively by authors	Deductive	12
Orr and Moon	Loma Linda University Medical Center, Loma Linda, Calif.	Academic	--	Aug. 1990-July 1991	12	46	144	Ethical issues identified retrospectively by requestor	Deductive, based on La Puma et al.[8]	19
Orr and Perkin	Loma Linda University Medical Center, Loma Linda, Calif.	Academic	≤ 18 years old	Aug. 1990-July 1992	24	64	179	Ethical issues identified retrospectively by consultant	--	21
Perkins and Saathoff	University of Texas Health Science Center, San Antonio, Tex.	Academic	--	Jan. 1984-June 1985	18	44	97	Ethical issues identified retrospectively by consultant	--	15
Ramsauer and Frewer	Erlangen University Hospital, Erlangen, Germany	Academic	Pediatric	2002-2008	84	16	NS	Reason for consultation and "Consultation Contents" identified retrospectively by authors	--	8
Romano et al.	Columbia University Medical Center, New York, N.Y.	Academic	Intensive care unit	Aug. 2006-July 2007	12	168	198	Ethical issue identified retrospectively by authors	Deductive, used Swetz, Crowley, Hook, and Mueller[9]	
Schenkenberg	Salt Lake VA Medical Center, Salt Lake City, Utah	Veterans Admini-stration	--	Jan. 1987-April 1996	124	160	249	Ethical issues	--	29
Shuman et al. (Sept. 2013)	National Cancer Institute designated comprehen-sive cancer centers[3]	Specialty	Adult oncology	2007-2011	48	208	NS	Reason for consultation identified prospectively	Deductive, based on Nilson, Tamer-in, and Fins[10]	8

Table 1. Continued next page.

TABLE 1. Characteristics of studies, *continued*

Article authors	Institution	Institution type	Study population	Data collection period	Duration of data collection (months)	Number of consultations	Total number of reasons or issues	Primary outcome measure	Derivation of typology	Number of categories
Shuman et al. (Nov. 2013)	Memorial Sloan-Kettering Cancer Center, New York, N.Y.	Specialty	Head and neck cancer	2007-2011	60	14	14	Reason for consultation identified prospectively	Deductive, based on Nilson, Tamerin, and Fins[11]	13
Streuli et al.	Zurich University Children's Hospital, Zurich, Switzerland	Children's	--	Jan. 2006-Dec. 2010	60	95	95	Ethical issues	--	11
Swetz, Crowley, Hook, and Mueller (June 2007)	Mayo Clinic, Rochester, Minn.	Academic	--	April 1995-Dec. 2005	129	255	1,181	Reason for consultation identified prospectively	Deductive	19
Swetz, Crowley, Hook, and Mueller (Dec. 2007)	Mayo Clinic, Rochester, Minn.	Academic	Neurological diagnosis	April 1995-Dec. 2005	120	47	129	Reason for consultation identified prospectively	Deductive, used Swetz, Crowly, Hook, and Mueller[12]	11
Tapper, Vercler, Cruze, and Sexson	Atlanta, Ga.[4]	Academic	--	2004-2006	36	285	7,598	Ethical issues identified retrospectively by consultant	--	32
Thomas et al.	Cleveland Clinic, Cleveland, Ohio	Academic	< 18 years of age. Presurgical neurologic consultations excluded	Jan. 2005-July 2013	106	102	261	Ethical issues identified by consultant	Inductive	29
Voigt et al.	Memorial Sloan-Kettering Cancer Center, New York, N.Y.	Specialty	Medical-surgical intensive care unit	Sept. 2007-Dec. 2011	52	53	53	Reasons for consultation identified retrospectively by authors	Deductive, used Nilson, Acres, Tamerin and Fins[13]	8
Wasson et al.	Loyola University Medical Center, Chicago, Ill.	Academic	--	2008-2013	60	156	53	Ethical issues identified retrospectively by authors	Both	40
Yen and Schneiderman	San Diego Children's Hospital and Health Center, San Diego, Calif.	Children's	--	Sept. 1990-April 1995	68	23	34	Ethical issues identified by consultant	--	5

NOTES

See the appendix for an alphabetical list of these articles. The column "Number of consultations" is the number of consultations analyzed, but may not be the total number of consultations during this time period. Some studies excluded some consultations based on type and/or completeness of records. The column "Primary outcome measure" is reported in the following format: reason for consultation or ethical issue identified prospectively or retrospectively by the requestor,

consultant, or authors; missing components were not specified in the article. NS = not specified.
1. Japanese medical institutions.
2. Two large medical centers in Manhattan, three community teaching hospitals in Brooklyn and Queens, and two community teaching hospitals in northern New Jersey.
3. One freestanding urban cancer center in a Northeastern metropolis, and one cancer center integrated within a large academic health system in a small Midwestern city.
4. A large urban public teaching hospital.
5. E. Fox, S. Myers, and R.A. Pearlman, "Ethics Consultation in United States Hospitals: A National Survey," *American Journal of Bioethics* 7, no. 2 (February 2007): 13-25.
6. This is the total number of reasons identified by the consulting physician.
7. Ibid.
8. J. La Puma et al., "An Ethics Consultation Service in a Teaching Hospital. Utilization and Evaluation," *Journal of the American Medical Association* 260, no. 6 (12 August 1988): 808-11.
9. K.M. Swetz, M.E. Crowley, C. Hook, and P.S. Mueller, "Report of 255 Clinical Ethics Consultations and Review of the Literature," *Mayo Clinic Proceedings* 82, no. 6 (June 2007): 686-91.
10. E.G. Nilson, C.A. Acres, N.G. Tamerin, and J.J. Fins, "Clinical Ethics and the Quality Initiative: A Pilot Study for the Empirical Evaluation of Ethics Case Consultation," *American Journal of Medical Quality* 23, no. 5 (September-October 2008): 356-64.
11. Ibid.
12. Swetz, Crowley, Hook, and Mueller, "Report of 255 Clinical Ethics Consultations," see note 9 above.
13. Nilson, Acres, Tamerin, and Fins, "Clinical Ethics and the Quality Initiative," see note 10 above.

RESULTS

Study Characteristics

The literature search, performed on 30 December 2016, identified 394 articles. Of these, 359 were excluded based on a review of the titles and abstracts, and 21 were excluded based on a review of the full text. An additional 34 articles were identified from references, and 18 of these were excluded based on a review of their full text. For example, articles that reported on clinician focus groups,[16] a survey of ethics committee chairs,[17] and published professional codes[18] were excluded. Of the 394 articles, 30 met our inclusion criteria and are included in this review. (See the appendix for a bibliography of the 30 articles.) Figure 1 depicts the data-extraction process.

Studies were conducted in the U.S. and a number of other countries including Australia,[19] Germany,[20] Japan,[21] Norway,[22] and Switzerland.[23] (See table 1.) The majority of studies were conducted at academic medical centers (n = 17). Cleveland Clinic,[24] Loma Linda University Medical Center,[25] Mayo Clinic,[26] and University of Chicago Hospitals[27] were the subject of multiple reports. A number of studies were conducted at children's hospitals or focused on pediatric patients (n = 9). Other sites included community hospitals,[28] health systems,[29] specialty hospitals,[30] and Veterans Affairs hospitals.[31] Several studies focused on specific patient populations including neurology patients,[32] trauma patients,[33] and patients with cancer.[34]

The earliest study was published in 1987.[35] The duration of data collection ranged from one month[36] to 241 months.[37] Some of the studies excluded consultations for a variety of reasons, and the resulting number of consultations ranged from 14[38] to 478.[39]

The studies described their primary outcomes in a variety of ways; 14 typologies described the reasons that triggered the consultation; 13 described the issues identified during the consultation. Of the 30 articles, 11 studies reported one ethical issue per consultation, 16 reported one or more issues, and three did not specify the number of issues. The articles differed regarding whether the issues were identified prospectively or retrospectively, or by the requestor, the consultant, or the investigator.

Content of the Typologies

The 30 articles that met our inclusion criteria included 27 unique typologies (a table of all of the typologies is available from the corresponding author). Three articles utilized previously published typologies: Swetz, Crowley, Hook, and colleagues[40] utilized their previously developed typology;[41] Romano, Wahlander, Lang, and colleagues[42] utilized a typology developed by Swetz, Crowley, Hook, and colleagues;[43] and Voigt, Rajendram, Shuman, and colleagues[44] utilized a typology developed by Nilson, Acres, Tamerin, and Fins.[45] While four articles reported that they utilized existing typologies, the categories included were not identical to the previously published typology, and they were included as distinct typologies.[46]

TABLE 2. Contents of typologies

Code	Numer of typologies that include code	% of typologies that include code	Henriksen Hellyer et al.	Moeller et al.	Nilson, Acres, Tamerin, and Fins	Orr and Moon	Shuman et al. (Nov. 2013)	Swetz, Crowley, Hook, and Mueller	Wasson et al.	Boissy, Ford, Edgell, and Furlan	Johnson, Church, Meltzer, and Baker
Number of the 5 most common codes	--	--	5	5	5	5	5	5	5	4	4
DNAR orders	19	70	X	X	X	X	X	X	X	X	X
Capacity	18	67	X	X	X	X	X	X	X	X	X
Withholding	18	67	X	X	X	X	X	X	X		X
Withdrawing	17	63	X	X	X	X	X	X	X	X	X
Surrogate or proxy	16	59	X	X	X	X	X	X	X	X	
Futility	15	56	X	X	X		X	X	X	X	X
Conflict cluster	15	56	X	X		X		X		X	X
Not otherwise specified	8	30				X				X	
Between patient/family and team	9	33	X	X						X	X
Family conflict	3	11						X			X
Within family	5	19								X	X
Within team	8	30						X		X	X
Life-sustaining treatment	14	52		X	X		X		X	X	X
Professionalism cluster	14	52	X			X	X	X	X		X
Not otherwise specified	8	30	X					X	X		X
Truth-telling	10	37	X			X	X				X
Boundaries	4	15	X								
Conflict of interest	2	7									X
Refusing treatment	14	52			X	X	X		X	X	X
Legal	13	48	X			X		X	X	X	
Resources	13	48	X			X	X	X			X
Advanced care planning	12	44	X		X		X	X	X	X	X
Autonomy	12	44	X			X		X	X	X	X
Medical subspecialty cluster	11	41						X	X	X	
Reproductive health	6	22						X	X		
Psychiatry	5	19						X		X	
Other	5	19							X		
Culture	10	37	X					X	X		X
Discharge	10	37				X	X	X	X		
Informed consent	10	37	X		X		X		X		
Privacy and confidentiality	10	37	X				X	X			X
Specific interventions	10	37				X	X		X	X	
Goals of care	9	33	X	X				X	X		X
Research	9	33	X					X			X
Death	8	30	X						X	X	
Decision making	8	30	X						X	X	X
End-of-life care	8	30						X	X		X
Communication	7	26	X							X	
Palliative care	7	26					X		X		X
Permission and assent	7	26	X						X		X
Quality of life	7	26						X	X		
Difficult patients	5	19	X								
Nonadherence	5	19	X	X							X
"Other"	5	19		X				X		X	
Best interest	3	11							X		
Demanding	3	11				X					X
Hastening death	3	11	X								
Justice	3	11	X								X
TOTAL number of codes			27	11	10	14	16	23	26	20	28

NOTES: Clusters do not count towards the total. See the appendix for a bibliography of these articles.

La Puma, Stocking, Darling, and Siegler	La Puma et al.	La Puma	Orr and Perkin	Perkins and Saathoff	Shuman et al. (Sept. 2013)	Tapper, Vercler, Cruze, and Sexson	Johnson, Lesandrini, and Rozycki	Schenkenberg	Steuli et al.	Forde and Vandvik	Fukuyama, Asai, Itai, and Bito	Opel et al.	Thomas et al.	Yen and and Schneiderman	Bruce, Smith, Hizlan, and Sharp	McDougall and Notini	Ramsauer and Frewer
4	4	4	4	4	4	4	3	3	3	2	2	1	1	1	0	0	0
X	X	X	X	X	X	X	X	X	X								
X	X	X	X	X			X	X			X		X				
X	X	X	X	X	X	X			X	X				X			
X	X	X			X	X			X	X	X						
			X	X	X	X	X	X				X					
			X		X	X	X		X		X						
X	X		X			X		X	X				X	X		X	X
X	X		X											X			X
			X			X		X	X							X	
									X								
			X			X										X	
			X			X		X	X				X				
X	X	X		X	X	X	X				X						
X						X	X	X									
X	X		X			X		X	X	X		X	X			X	
X										X	X		X			X	
	X							X									
						X			X	X		X	X			X	
X			X			X	X	X			X						
	X		X					X					X	X			
X					X	X	X	X			X	X	X				
X		X				X	X	X			X						
			X	X		X		X									X
						X		X									X
X		X	X					X				X	X		X		
X		X				X	X	X									
							X		X		X		X		X		
		X	X				X				X		X				
						X			X			X	X		X		
		X				X				X		X	X				
				X									X				
X			X			X						X	X			X	
							X		X		X		X		X		
						X						X	X				
X	X																
											X						X
				X													
	X						X										
											X						X
18	**14**	**13**	**16**	**10**	**9**	**26**	**18**	**17**	**12**	**5**	**14**	**9**	**20**	**4**	**6**	**6**	**6**

The studies developed their typologies using a variety of methods. They characterized the consultations deductively based on *a priori* categories or a review of the literature (n = 8), inductively based on categories developed from a qualitative analysis of the cases (n = 2), or based on a combination of both approaches (n = 3). Some studies categorized their consultations based on a published coding catalog or typology.[47] Almost half of the studies (14) did not state how they developed their categories. Only two studies included examples of their categories[48] and only one included a code book with definitions.[49]

All but one of the studies presented their typologies in a table, figure, or box.[50] Of these, 11 typologies were divided into major headings and subcategories. The number of categories in each typology ranged from five to 47 (mean = 18).

We created 45 codes based on the concepts that appeared in the published typologies (see table 2). The most commonly used codes were "DNAR orders" (19 typologies, 70 percent), "capacity" (18 typologies, 67 percent), "withholding" (18 typologies, 67 percent), "withdrawing" (17 typologies, 63 percent), and "surrogate or proxy" (16 typologies, 59 percent). Seven (26 percent) of the typologies contained all five of the most frequently appearing codes. None of the typologies contained all 10 of the most frequently used codes; two typologies contained nine of the 10 most frequently used codes.[51] One typology contained none of the 10 most frequently used codes.[52]

Some codes were related to ethical principles—for example, "autonomy" and "justice"—or ethical issues—for example, "DNAR [do-not-attempt-resuscitation] orders," "capacity," "surrogate or proxy," "advance care planning," "informed consent," and "privacy and confidentiality." Other codes referred to decision making in general, for example, "decision making" and "goals of care," decision making dynamics, for example, "withholding," "withdrawing," "refusing," and "demanding," or types of interventions, for example, "DNAR orders," "life-sustaining treatment," "end-of-life care," and "palliative care," without specifying specific ethical issues. Finally, some codes identified sources of ethical norms without specifying particular ethical issues, for example, "legal" and "culture," which included religion, specific religious groups, and spirituality.

DISCUSSION

Our systematic review identified 30 articles containing 27 unique typologies of the reasons for or ethical issues identified in clinical ethics consultations. The studies varied in type of institution, duration of data collection, number of consultations, primary outcome measure, and number of categories and typology. The number of categories in each typology ranged from five to 47 (mean = 18). The most commonly used codes were "DNAR orders," "capacity," "withholding," "withdrawing," and "surrogate or proxy." Only seven of the 27 (26 percent) contained all five of the most common codes.

While evaluation of the reasons for clinical ethics consultations has generated a substantial body of literature, this literature has a number of limitations. First, the studies utilized a variety of primary outcome measures. It may be beneficial to identify the benefits and detriments of focusing on the perspectives of the requestor, the consultant, or the investigator as well as the benefits and detriments of prospective and retrospective coding. Furthermore, some studies identified a single ethical issue per consultation, and others multiple ethical issues per consultation. It was not clear how the former studies identified the most important issue.

Second, 13 studies did not specify how they developed their typologies, and those that did specify used a variety of methods. Ideally, one might use both deductive and inductive approaches, draw on ethical theory and the published literature, as well as analyses of the consultations themselves. Some of the typologies did not include important ethical concepts, for example, Moeller and colleagues did not include "privacy and confidentiality."[53] Collaboration will be required to overcome the limitations of inductive analyses of consultations from one institution; for example, augmenting the experience of institutions that do not provide obstetric or pediatric care with those that do.

Third, there was no standard typology; the existing typologies were significantly heterogeneous. There was no consensus on even the most frequent codes. For example, "DNAR orders," the most frequent code, did not appear in almost one-third of the studies. This lack of uniformity made it difficult to compare institutional experiences; for example, how did the reasons for consultations differ between types of institutions, institutions in different geographic re-

gions, or methods of clinical ethics consultation.[54]

Fourth, with one exception, the studies did not provide a code book with clear definitions or examples of their categories.[55] This made coding and interpretation of some of the categories more subjective. For example, "family conflict," which appeared in three typologies, is ambiguous; it is unclear whether it referred to conflict between the family and the medical staff and/or conflict within the family. Additionally, typologies included categories that were difficult to distinguish from each other, for example, separate categories for "constrained decision making" and "threatened autonomy."[56] A lack of well-defined categories made it difficult for institutions that wished to utilize an existing typology to apply it consistently. Additional research is needed to establish the reliability of different raters applying a typology's categories.

Fifth, many of the typologies included multiple, conceptually distinct topics in a single typology.[57] For example, some typologies included categories for "conflict and/or types of conflict." Consultations may be the result of either dilemmas or conflicts. There may be uncertainty about the ethical issue, or interpersonal conflict regarding the ethical issue, but the dynamic is separate from the ethical issue itself. Other typologies included categories regarding particular types of treatment, for example, "DNAR orders," "end-of-life care," and "palliative care." It was unclear whether these categories identified specific ethical issues or clinical scenarios. Finally, some typologies included categories that were coded as "culture" or "legal." These categories generally identified a source of ethical norms rather than the ethical issue; they generally modified rather than characterized the ethical issue. It would have been clearer for typologies to treat these topics as separate issues rather than include them in a single typology. For example, Johnson, Church, Metzger, and Baker[58] distinguished the primary reason for a consult request and involvement of external services (chaplaincy, palliative care, legal, and child protective services); Henriksen Hellyer and colleagues[59] distinguished "evidence of interpersonal conflict," "interpersonal conflict type," "primary reason for consult," "legal involvement," and "consult and end of live [*sic*]".

These limitations suggest the need for a uniform typology. Such a typology would have a number of benefits: it could support clinical practice, scholarship, and professionalization. Data on the frequency of different ethical issues could, for example, inform the development of specified content for a certification examination for clinical ethics consultants. The development and adoption of a uniform typology would be facilitated by collaboration among a variety of institutions. This would provide a diversity of perspectives in developing a typology and promote investment in utilizing the resulting product. Professional organizations could play a crucial role in funding and coordinating the development process.

This systematic review has several limitations. It only retrieved published typologies and did not include typologies that were not published in the scholarly literature. Our utilization of a single database, PubMed, and language, English, may have inadvertently excluded some published clinical ethics typologies. Our review also only retrieved typologies that were published in particular types of articles. The review may, therefore, have omitted some typologies. It, nonetheless, resulted in relatively large listing of typologies. Our preconceptions or biases may have inadvertently influenced our coding of the data. The heterogeneity of the typologies prevents a meta-analysis of the results of the studies.

Our systematic literature review of typologies of clinical ethics consultation identified 30 articles and 27 unique typologies. The studies varied in terms of institution type, geographic location, time frame, and number of consultations. The studies used different primary outcome measures. The typologies differed from one another in number and types of categories, which made comparisons between the studies difficult. This suggests the need for a uniform typology with clear definitions to advance practice and scholarship within the field. We believe that such a typology will provide a common language and framework to categorize consultations and compare consultation patterns.

ACKNOWLEDGMENTS

The authors wish to thank Alison Kissling, MLIS, Cincinnati Children's Hospital Medical Center, and Martina Darragh, MLS, the Kennedy Institute of Ethics, for their assistance in developing the search strategy and conducting the research, and Jennifer Longbottom for verifying the abstraction of data.

NOTES

1. S.J. Youngner et al.,"A National Survey of Hospital Ethics Committees," *Critical Care Medicine* 11, no. 11 (November 1983): 902-05.

2. E. Fox, S. Myers, and R.A. Pearlman, "Ethics Consultation in United States Hospitals: A National Survey," *American Journal of Bioethics* 7, no. 2 (February 2007): 13-25.

3. M.P. Aulisio, R.M. Arnold, and S.J. Youngner, "Health Care Ethics Consultation: Nature, Goals, and Competencies: A Position Paper from the Society for Health and Human Values-Society for Bioethics Consultation Task Force on Standards for Bioethics Consultation," *Annuals of Internal Medicine* 133, no. 1 (4 July 2000): 59-69; J.C. Fletcher and M. Siegler, "What Are the Goals of Ethics Consultation? A Consensus Statement," *The Journal of Clinical Ethics* 7, no. 2 (Summer 1996): 122-6.

4. L.J. Schneiderman et al.,"Effect of Ethics Consultations on Nonbeneficial Life-Sustaining Treatments in the Intensive Care Setting: A Randomized Controlled Trial," *Journal of the American Medical Association* 290, no. 9 (3 September 2003): 1166-72; SUPPORT, "A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients: The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT): The SUPPORT Principal Investigators," *Journal of the American Medical Association* 274, no. 20 (22-29 November 1995): 1591-8.

5. L.M. Johnson, C.L. Church, M. Metzger, and J.N. Baker, "Ethics Consultation in Pediatrics: Long-Term Experience from a Pediatric Oncology Center," *American Journal of Bioethics* 15, no. 5 (2015): 3-17.

6. A.H. Antommaria, "Characterizing Clinical Ethics Consultations: The Need for a Standardized Typology of Cases," *American Journal of Bioethics* 15, no. 5 (2015): 18-20.

7. J. Henriksen Hellyer et al.,"Pediatric Clinical Ethics Consultations at an Academic Medical Center: Does One Size Fit All?" *American Journal of Bioethics* 15, no. 5 (2015): 20-4.

8. L. Gillam, R. McDougall, and C. Delany, "Making Meaning from Experience: A Working Typology for Pediatrics Ethics Consultations," *American Journal of Bioethics* 15, no. 5 (2015): 24-6.

9. "Prospero is an international prospective register of systematic reviews. . . . relevant to health and social care, welfare, public health, education, crime, justice, and international development, where there is a health related outcome." *https://www.crd.york.ac.uk/prospero/.*

10. D.J. Opel et al.,"Characterisation of Organisational Issues in Paediatric Clinical Ethics Consultation: A Qualitative Study," *Journal of Medical Ethics* 35, no. 8 (August 2009): 477-82.

11. S. Merriam, *Qualitative Research: A Guide to Design and Implementation* (San Francisco, Calif.: Jossey-Bass, 2009).

12. Opel et al.,"Characterisation of Organisational Issues," see note 10 above.

13. T. Schenkenberg, "Salt Lake City VA Medical Center's First 150 Ethics Committee Case Consultations: What We Have Learned (So Far)," *HEC Forum* 9, no. 2 (June 1997): 147-58.

14. T. Ramsauer and A. Frewer, "Clinical Ethics Committees and Pediatrics: An Evaluation of Case Consultations,"*Diametros* 22 (2009): 90-104.

15. D. Hruschka et al., "Reliability in Coding Open-Ended Data: Lessons Learned from HIV Behavioral Research," *Field Methods* 16, no. 3 (2004): 307-31.

16. N. Cobanoglu and L. Algier, "A Qualitative Analysis of Ethical Problems Experienced by Physicians and Nurses in Intensive Care Units in Turkey," *Nursing Ethics* 11, no. 5 (September 2004): 444-58.

17. G. McGee et al., "Successes and Failures of Hospital Ethics Committees: A National Survey of Ethics Committee Chairs," *Cambridge Quarterly of Healthcare Ethics* 11, no. 1 (Winter 2002): 87-93.

18. L.S. Robins, C.H. Braddock, and K.A. Fryer-Edwards, "Using the American Board of Internal Medicine's 'Elements of Professionalism' for Undergraduate Ethics Education," *Academic Medicine* 77, no. 6 (June 2002): 523-31.

19. R.J. McDougall and L. Notini, "What Kinds of Cases Do Paediatricians Refer to Clinical Ethics? Insights from 184 Case Referrals at an Australian Paediatric Hospital," *Journal of Medical Ethics* 42, no. 9 (September 2016): 586-91.

20. Ramsauer and Frewer, "Clinical Ethics Committees and Pediatrics," see note 14 above.

21. M. Fukuyama, A. Asai, K. Itai, and S. Bito, "A Report on Small Team Clinical Ethics Consultation Programmes in Japan," *Journal of Medical Ethics* 34, no. 12 (December 2008): 858-62.

22. R. Forde and I.H. Vandvik, "Clinical Ethics, Information, and Communication: Review of 31 Cases from a Clinical Ethics Committee," *Journal of Medical Ethics* 31, no. 2 (February 2005): 73-7.

23. J.C. Streuli et al., "Five-Year Experience of Clinical Ethics Consultations in a Pediatric Teaching Hospital," *European Journal of Pediatrics* 173, no. 5 (May 2014): 629-36.

24. A.R. Boissy, P.J. Ford, R.C. Edgell, and A.J. Furlan, "Ethics Consultations in Stroke and Neurological Disease: A 7-Year Retrospective Review," *Neurocritical Care* 9, no. 3 (2008): 394-9; C.R. Bruce, M.L. Smith, S. Hizlan, and R.R. Sharp, "A Systematic Review of Activities at a High-Volume Ethics Consultation Service," *The Journal of Clinical Ethics* 22, no. 2 (Summer 2011): 151-64; S.M. Thomas et al.,"Not Just Little Adults: A Review of 102 Paediatric Ethics Consultations," *Acta Paediatrica* 104, no. 5 (May 2015): 529-34.

25. R.D. Orr and E. Moon, "Effectiveness of an Ethics Consultation Service," *Journal of Family Practice* 36, no. 1 (January 1993): 49-53; R.D. Orr and R.M. Perkin, "Clinical Ethics Consultations with Children," *The Journal of Clinical Ethics* 5, no. 4 (Winter 1994): 323-28.

26. Henriksen Hellyer et al.,"Pediatric Clinical Ethics Consultations," see note 7 above; K.M. Swetz, M.E. Crowley, C. Hook, and P.S. Mueller, "Ethics Consultations and Patients with Neurological Diseases: Author Reply," *Mayo Clinic Proceedings* 82, no. 12 (December 2007): 1577-8; K.M. Swetz, M.E. Crowley, C. Hook, and P.S. Mueller, "Report of 255 Clinical Ethics Consultations and Review of the Literature," *Mayo Clinic Proceedings* 82, no. 6 (June 2007): 686-91.

27. J. La Puma et al., "An Ethics Consultation Service in a Teaching Hospital: Utilization and Evaluation," *Journal of the American Medical Association* 260, no. 6 (12 August 1988): 808-11; J. La Puma, C.B. Stocking, C.M. Darling, and M. Siegler, "Community Hospital Ethics Consultation: Evaluation and Comparison with a University Hospital Service," *American Journal of Medicine* 92, no. 4 (April 1992): 346-51.

28. J. La Puma, "Consultations in Clinical Ethics—Issues and Questions in 27 Cases," *Western Journal of Medicine* 146, no. 5 (May 1987): 633-7.

29. E.G. Nilson, C.A. Acres, N.G. Tamerin, and J.J. Fins, "Clinical Ethics and the Quality Initiative: A Pilot Study for the Empirical Evaluation of Ethics Case Consultation," *American Journal of Medical Quality* 23, no. 5 (September-October 2008): 356-64.

30. Johnson, Church, Metzger, and Baker, "Ethics Consultation in Pediatrics," see note 5 above.

31. Schenkenberg, "Salt Lake City VA," see note 13 above.

32. Boissy, Ford, Edgell, and Furlan, "Ethics Consultations in Stroke and Neurological Disease," see note 24 above; Swetz, Crowley, Hook, and Mueller, "Ethics Consultations," see note 26 above.

33. L.S. Johnson, J. Lesandrini, and G.S. Rozycki, "Use of the Medical Ethics Consultation Service in a Busy Level I Trauma Center: Impact on Decision-Making and Patient Care," *American Journal of Surgery* 78, no. 7 (July 2012): 735-40.

34. A.G. Shuman et al., "Clinical Ethics Consultation in Patients with Head and Neck Cancer," *Head & Neck* 35, no. 11 (November 2013): 1647-51; A.G. Shuman et al., "Clinical Ethics Consultation in Oncology," *Journal of Oncology Practice* 9, no. 5 (September 2013): 240-5.

35. La Puma, "Consultations in Clinical Ethics," see note 28 above.

36. Nilson, Acres, Tamerin, and Fins, "Clinical Ethics and the Quality Initiative," see note 29 above.

37. Henriksen Hellyer et al.,"Pediatric Clinical Ethics Consultations," see note 7 above.

38. Shuman et al.,"Clinical Ethics Consultation," see note 34 above.

39. Bruce, Smith, Hizlan, and Sharp, "A Systematic Review," see note 24 above.

40. Swetz, Crowley, Hook, and Mueller, "Ethics Consultations," see note 26 above.

41. Swetz, Crowley, Hook, and Mueller, "Report of 255," see note 26 above.

42. M.E. Romano et al.,"Mandatory Ethics Consultation Policy," *Mayo Clinic Proceedings* 84, no. 7 (July 2009): 581-5.

43. Swetz, Crowley, Hook, and Mueller, "Report of 255," see note 26 above.

44. L.P. Voigt et al.,"Characteristics and Outcomes of Ethics Consultations in an Oncologic Intensive Care Unit," *Journal of Intensive Care Medicine* 30, no. 7 (October 2015): 436-42.

45. Nilson, Acres, Tamerin, and Fins, "Clinical Ethics and the Quality Initiative," see note 29 above.

46. La Puma, Stocking, Darling, and Siegler, "Community Hospital Ethics Consultation," see note 27 above; La Puma et al., "An Ethics Consultation Service in a Teaching Hospital," see note 27 above; Shuman et al., "Clinical Ethics Consultation," see note 34 above; Shuman et al., "Clinical Ethics Consultation in Oncology," see note 34 above.

47. Johnson, Lesandrini, and Rozycki, "Use of the Medical Ethics Consultation," see note 33 above; La Puma et al., "An Ethics Consultation Service in a Teaching Hospital," see note 27 above; Shuman et al., "Clinical Ethics Consultation," see note 34 above; Shuman et al., "Clinical Ethics Consultation in Oncology," see note 34 above.

48. Johnson, Church, Metzger, and Baker, "Ethics Consultation in Pediatrics," see note 5 above; McDougall and Notini, "What Kinds of Cases Do Paediatricians Refer?" see note 19 above.

49. Johnson, Lesandrini, and Rozycki, "Use of the Medical Ethics Consultation," see note 33 above.

50. Nilson, Acres, Tamerin, and Fins, "Clinical Ethics and the Quality Initiative," see note 29 above.

51. Shuman et al., "Clinical Ethics Consultation in Oncology," see note 34 above; K. Wasson et al., "What Ethical Issues Really Arise in Practice at an Academic Medical Center? A Quantitative and Qualitative Analysis of Clinical Ethics Consultations from 2008 to 2013," *HEC Forum* 28, no. 3 (September 2016): 217-28.

52. Bruce, Smith, Hizlan, and Sharp, "A Systematic Review," see note 24 above.

53. J.R. Moeller et al., "Functions and Outcomes of a Clinical Medical Ethics Committee: A Review of 100 Consults," *HEC Forum* 24, no. 2 (June 2012): 99-114.

54. Antommaria, "Characterizing Clinical Ethics Consultations," see note 6 above; Henriksen Hellyer et al., "Pediatric Clinical Ethics Consultations," see note 7 above.

55. Johnson, Lesandrini, and Rozycki, "Use of the Medical Ethics Consultation," see note 33 above.

56. Johnson, Church, Metzger, and Baker, "Ethics Consultation in Pediatrics," see note 5 above.

57. Antommaria, "Characterizing Clinical Ethics Consultations," see note 6 above; Henriksen Hellyer et al.,"Pediatric Clinical Ethics Consultations," see note 7 above.

58. Johnson, Church, Metzger, and Baker, "Ethics Consultation in Pediatrics," see note 5 above.

59. Henriksen Hellyer et al.,"Pediatric Clinical Ethics Consultations," see note 7 above.

APPENDIX

Boissy, A.R., P.J. Ford, R.C. Edgell, and A.J. Furlan. "Ethics Consultations in Stroke and Neurological Disease: A 7-Year Retrospective Review." *Neurocritical Care* 9, no. 3 (2008): 394-9.

Bruce, C.R., M.L. Smith, S. Hizlan, and R.R. Sharp. "A Systematic Review of Activities at a High-Volume Ethics Consultation Service." *The Journal of Clinical Ethics* 22, no. 2 (Summer 2011): 151-64.

Forde, R., and I.H. Vandvik. "Clinical Ethics, Information, and Communication: Review of 31 Cases from a Clinical Ethics Committee." *Journal of Medical Ethics* 31, no. 2 (February 2005): 73-7.

Fukuyama, M., A. Asai, K. Itai, and S. Bito. "A Report on Small Team Clinical Ethics Consultation Programmes in Japan." *Journal of Medical Ethics* 34, no. 12 (December 2008): 858-62.

Henriksen Hellyer, J. et al. "Pediatric Clinical Ethics Consultations at an Academic Medical Center: Does One Size Fit All?" *American Journal of Bioethics* 15, no. 5 (2015): 20-4.

Johnson, L.M., C.L. Church, M. Metzger, and J.N. Baker. "Ethics Consultation in Pediatrics: Long-Term Experience from a Pediatric Oncology Center." *American Journal of Bioethics* 15, no. 5 (2015): 3-17.

Johnson, L.S., J. Lesandrini, and G.S. Rozycki. "Use of the Medical Ethics Consultation Service in a Busy Level I Trauma Center: Impact on Decision-Making and Patient Care." *American Journal of Surgery* 78 no. 7 (July 2012): 735-40.

La Puma, J. "Consultations in Clinical Ethics—Issues and Questions in 27 Cases." *Western Journal of Medicine* 146, no. 5 (May 1987): 633-7.

La Puma, J. et al. "An Ethics Consultation Service in a Teaching Hospital: Utilization and Evaluation." *Journal of the American Medical Association* 260, no. 6 (12 August 1988): 808-11.

La Puma, J., C.B. Stocking, C.M. Darling, and M. Siegler. "Community Hospital Ethics Consultation: Evaluation and Comparison with a University Hospital Service." *American Journal of Medicine* 92, no. 4 (April 1992): 346-51.

McDougall, R.J., and L. Notini. "What Kinds of Cases Do Paediatricians Refer to Clinical Ethics? Insights from 184 Case Referrals at an Australian Paediatric Hospital." *Journal of Medical Ethics* 42, no. 9 (September 2016): 586-91.

Moeller, J.R. et al. "Functions and Outcomes of a Clinical Medical Ethics Committee: A Review of 100 Consults." *HEC Forum* 24, no. 2 (June 2012): 99-114.

Nilson, E.G., C.A. Acres, N.G. Tamerin, and J.J. Fins. "Clinical Ethics and the Quality Initiative: A Pilot Study for the Empirical Evaluation of Ethics Case Consultation." *American Journal of Medical Quality* 23, no. 5 (September-October 2008): 356-64.

Opel, D.J. et al. "Characterisation of Organisational Issues in Paediatric Clinical Ethics Consultation: A Qualitative Study." *Journal of Medical Ethics* 35, no. 8 (August 2009): 477-82.

Orr, R.D., and E. Moon. "Effectiveness of an Ethics Consultation Service." *Journal of Family Practice* 36, no. 1 (January 1993): 49-53.

Orr, R.D., and R.M. Perkin. "Clinical Ethics Consultations with Children." *The Journal of Clinical Ethics* 5, no. 4 (Winter 1994): 323-8.

Perkins, H.S., and B.S. Saathoff. "Impact of Medical Ethics Consultations on Physicians: An Exploratory Study." *American Journal of Medicine* 85, no. 6 (December 1988): 761-65.

Ramsauer, T., and A. Frewer. "Clinical Ethics Committees and Pediatrics: An Evaluation of Case Consultations." *Diametros* 22 (2009): 90-104.

Romano, M.E. et al. "Mandatory Ethics Consultation Policy." *Mayo Clinic Proceedings* 84, no. 7 (July 2009): 581-5.

Schenkenberg, T. "Salt Lake City VA Medical Center's First 150 Ethics Committee Case Consultations: What We Have Learned (So Far)." *HEC Forum* 9, no. 2 (June 1997): 147-58.

Shuman, A.G. et al. "Clinical Ethics Consultation in Oncology." *Journal of Oncology Practice* 9, no. 5 (September 2013): 240-5.

Shuman, A.G. et al. "Clinical Ethics Consultation in Patients with Head and Neck Cancer." *Head & Neck* 35, no. 11 (November 2013): 1647-51.

Streuli, J.C. et al. "Five-Year Experience of Clinical Ethics Consultations in a Pediatric Teaching Hospital." *European Journal of Pediatrics* 173, no. 5 (May 2014): 629-36.

Swetz, K.M., M.E. Crowley, C. Hook, and P.S. Mueller. "Report of 255 Clinical Ethics Consultations and Review of the Literature." *Mayo Clinic Proceedings* 82, no. 6 (June 2007): 686-91.

Swetz, K.M., M.E. Crowley, C. Hook, and P.S. Mueller. "Ethics Consultations and Patients with Neurological Diseases: Author Reply." *Mayo Clinic Proceedings* 82, no. 12 (December 2007): 1577-8.

Tapper, E.B., C.J. Vercler, D. Cruze, and W. Sexson. "Ethics Consultation at a Large Urban Public Teaching Hospital." *Mayo Clinic Proceedings* 85, no. 5 (May 2010): 433-8.

Thomas, S.M. et al. "Not Just Little Adults: A Review of 102 Paediatric Ethics Consultations." *Acta Paediatrica* 104, no. 5 (May 2015): 529-34.

Voigt, L.P. et al. "Characteristics and Outcomes of Ethics Consultations in an Oncologic Intensive Care Unit." *Journal of Intensive Care Medicine* 30, no. 7 (October 2015): 436-42.

Wasson, K. et al. "What Ethical Issues Really Arise in Practice at an Academic Medical Center? A Quantitative and Qualitative Analysis of Clinical Ethics Consultations from 2008 to 2013." *HEC Forum* 28, no. 3 (September 2016): 217-28.

Yen, B.M., and L.J. Schneiderman. "Impact of Pediatric Ethics Consultations on Patients, Families, Social Workers, and Physicians." *Journal of Perinatology* 19, no. 5 (July-August 1999): 373-8.

Justice and Respect for Autonomy: Jehovah's Witnesses and Kidney Transplant

Paul J. Cummins and Federico Nicoli

ABSTRACT

That Jehovah's Witnesses may refuse lifesaving blood transfusions is a morally accepted feature of contemporary medical practice. The principle of respect for autonomy supports this, and there is seldom reason to interfere with this choice because it rarely harms another individual. Advances in surgical technique have made it possible for transplant surgeons to perform bloodless organ transplant, enabling Jehovah's Witnesses to benefit from this treatment. When the transplant organ is a directed donation from a family member or friend, no ethical dilemma arises. However, when a Jehovah's Witness cannot identify a living donor and wishes to be listed for organ transplant, the transplant team may face an ethical dilemma. On the one hand, it wishes to provide care to the patient that is compatible with her or his preferences. On the other hand, the team may wonder if it is fair to other patients who need an organ and will accept blood transfusion to include the Jehovah's Witness patient on a waiting list for a donated organ. If the Jehovah's Witness patient is listed and receives an organ, then a patient who also needs an organ, and who is willing to accept all care to optimize the success of the transplant, may be denied an organ.

To frame the ethical dilemma outlined above we present an anonymized case of a Jehovah's Witness woman in urgent need of a kidney, who was referred to one of the authors' institution's transplant center. We review the evolution of the Jehovah's Witness position on blood transfusion and the medical community's efforts to provide care that accommodates this religious commitment. If Witnesses are to be denied transplant in the name of justice, there must be an ethically sound reason. We identify two rationales in the literature: (1) this allocation is unacceptable because it will cost lives; (2) resources should be allocated to patients who comply with the standard of care. We argue that neither apply to this dilemma. We also emphasize the importance of examining the data on outcomes of transplant with and without transfusion. Our interpretation of the published data on transplant without transfusion is that the outcomes are similar. We conclude that, in the absence of data that resources are risked, it is not ethical to refuse to include a Jehovah's Witness patient on a waiting list for an organ. Finally, we reflect on the heterogeneity in transplant institutes' polices for accepting Jehovah's Witness patients.

Paul J. Cummins, PhD, is an Assistant Professor of Medical Education at the Icahn School of Medicine at Mount Sinai in New York, New York, and is a Member of its Bioethics Program. *paul.cummins @mssm.edu*

Federico Nicoli, PhD, is a Member of the Center for Clinical Ethics at Insubria University in Varese, Italy, and is a Consultant in the Clinical Ethics Service at Domus Salutis Clinic, Teresa Camplani Foundation, Brescia, Italy. *federico.nicoli82 @gmail.com*

INTRODUCTION

The medical community in the United States has a long record of adapting to the constraints

that the Jehovah's Witness faith imposes on medical care. For example, Denton Cooley, MD pioneered bloodless open-heart surgery.[1] In other countries, Jehovah's Witnesses comprise an emerging religious minority, but one which is rapidly growing, as in Italy, where one author is a clinical ethicist.[2] In countries where the medical community is less accustomed to interacting with Jehovah's Witnesses, medical professionals might judge that providing care that is consistent with a Witness's faith, which could result in the patient dying when, otherwise, he or she would heal, is incompatible with medical ethics. Their judgment might be reinforced if the Jehovah's Witness patient's choice negatively affects another patient's health. That this patient's death may also profoundly affect her family and friends is another consideration that could influence medical professional's judgment.

Jehovah's Witnesses' refusal of blood transfusion is, probably, the most well-known example of a religious-based refusal of medical intervention. The Jehovah's Witness religion, founded in 1872 in Pittsburgh, Pennsylvania, is administered by the Watchtower Bible and Tract Society of Pennsylvania (the Watchtower Society). In 1945, the Watchtower Society promulgated a doctrine that "Blood transfusions and blood products are officially banned as 'pagan and God-dishonoring,' " effectively forbidding Witnesses to accept them.[3] And in 1967, the Watchtower Society also imposed a ban on organ transplant.[4]

Between 1980 and 2000, the Watchtower Society revised its guidance to Jehovah's Witnesses on blood transfusion and organ transplant. In 1980, the Watchtower Society rejected the use of stored autologous blood for transfusion, but it did endorse a policy that Witnesses should consult their personal consciences to decide whether to accept acute normovolemic hemodilution (ANH), intraoperative blood salvage, and blood fractions like albumin, immune globulins, or clotting factors.[5] Jehovah's Witnesses continue to be directed to reject transfusion of whole blood, red blood cells, platelets, plasma, hemoglobin solution, stored autologous blood, and blood donation. The Watchtower Society also revised the choice to undergo organ transplant into a matter of personal conscience, reversing its previous guidance.[6]

In this article, we consider a case in which a Jehovah's Witness patient requested to be listed for organ transplant but requested a procedure compatible with the guidance from the Watchtower Society. For the sake of brevity, we will refer to an organ transplant that adheres to these constraints as "transfusion-free transplant." We address the ethical question of whether transplant teams are justified in refusing to list a Jehovah's Witness patient who requests transfusion-free transplant to ensure that organs are allocated to a patient who will accept all protocols for optimizing graft survival. While our focus is on kidney transplant, our argument could be relevant to heart, liver, lung, pancreas, and stem-cell transplant.

In the case we describe below, the transplant team at the Mount Sinai Hospital (MSH) Recanati/Miller Transplant Institute (RMTI) was unsure if listing a Jehovah's Witness for kidney transplant was ethical. It is important to address this issue because there is actually very little guidance within the bioethics literature for transplant surgeons to consult.

Our review of the bioethics literature reveals that there are only two articles that address the issue, and both argue that it is ethically acceptable for surgeons to make transfusion of whole blood a condition for transplant. This guidance, we believe, is wrong: transplant surgeons should not force a Jehovah's Witness patient to choose between her or his religious convictions and medical care.

We offer two reasons why the guidance is wrong. First, without empirical evidence that transfusion-free transplant compromises the survival of a graft, refusal to list a Jehovah's Witness is unfair discrimination. Second, we reject the argument that requiring blood transfusion as a condition for inclusion on the transplant list is ethical because Jehovah's Witnesses are not making autonomous decisions to refuse transfusion.

First, we present our case, and then we describe each article's distinct rationale for not listing Jehovah's Witnesses for organ transplant, and we offer conceptual rebuttals for them. We then review the medical literature on transfusion-free transplant to offer an empirical rebuttal of these rationales. Next, we consider and reject an argument that a Jehovah's Witness's refusal of blood transfusion is not an autonomous choice. Finally, we anticipate a potential criticism that the evidence about transfusion-free transplant in the medical literature fails to capture the risk in individual cases.

CASE

Our case is about a 61-year-old woman with kidney failure due to hypertension and diabetes mellitus, complicated by coronary artery disease and hepatitis C chronic infection, which she acquired from a blood transfusion following childbirth. In late 2013, she was referred to the RMTI because it has a program for kidney transplants from donors with hepatitis C infection to patients with hepatitis C.

The patient was receiving dialysis, but she did not tolerate it well because she experienced persistent chest/back pain, nausea, and mild hypotension within 15 to 30 minutes of the beginning of dialysis. In addition, her only dialysis access was through a thigh graft. The medical team was unsure how long it could maintain access for the patient's dialysis treatment. Because the patient was not able to find a living kidney donor and she faced the prospect of not being able to continue dialysis, she was in extreme need of a kidney transplant.

The transplant team had to decide if the patient was a candidate for registration for a kidney transplant with the Organ Procurement and Transplantation Network (OPTN). The decision to register the patient on OPTN became more complex when she informed the team that she would not accept blood transfusion or blood products because she was a Jehovah's Witness. The patient expressed a strong desire to undergo kidney transplant, but she was insistent that she would not accept blood transfusion or blood products. She expressed frustration with prior "ugly experiences" at other institutions, in which her commitment was "ridiculed," and physicians told her that they would transfuse her when she was unconscious. The patient understood that her health was precarious, but "it would be silly to make a decision that would displease Jehovah, when my life is at risk, especially if there are alternatives to transfusion."

The transplant team wanted to help the patient, but it also worried that it would harm another patient who would be willing to accept transfusion, if that patient was passed over for a kidney. The transplant team's ambivalence about whether or not to list the patient for transplant reflects uncertainty about how the principle of justice applied in this case, and the dilemma the team faced can be put as follows: is it just to allocate an organ to a patient whose autonomous request for transfusion-free transplant will be honored? To begin to answer that question, it is important to consider the validity of rationales for excluding a Jehovah's Witness patient as a transplant candidate.

ETHICAL GUIDANCE IN THE LITERATURE

Transplant teams who consult the medical ethics literature on this issue will find very few articles. We identified two articles that provided guidance on allocating organs for transplant to patients who requested transfusion-free transplant: Boggi and colleagues' "Kidney and pancreas transplants in Jehovah's Witnesses: ethical and practical implications," and Bramstedt's "Transfusion contracts for Jehovah's Witnesses receiving organ transplants: ethical necessity or coercive pact?"[7] Our primary objection to the arguments made by Boggi and colleagues and Bramstedt is that they fail to account for empirical evidence on transfusion-free transplant. We also find their arguments to be flawed. We will present and rebut the arguments in turn before discussing the evidence that refutes them.

Boggi and Colleagues' Rationale

Boggi and colleagues report that "most Jehovah's Witnesses can safely receive a kidney . . . transplant without transfusions. However, in a low, though not negligible, proportion of recipients, blood transfusions cannot be avoided without the risk of recipient death."[8] Their experience is that a risk of death is associated with post-operative complications, and they propose that making an agreement to rescue transfusion should be a condition for transplant. Boggi and colleagues acknowledge that, in medical care, patients are usually free to choose the medical interventions they will undergo. However, they claim that organ transplant is a unique form of medical care because patients' choices can "decrease the chance of other patients to timely obtain appropriate medical treatment."[9] Their concern is that permitting transfusion-free transplant puts more lives at risk than transplant with transfusion, as the patient who receives the organ but refuses transfusion will die, and a patient who may have received the organ instead will be at increased risk of dying. The authors' proposal to require rescue transfusion aims to optimize the possibility that a patient will benefit from the organ allocated to the patient. This

is a form of triage. If this triage rationale is applied to our case, the Jehovah's Witness patient would be deprioritized for organ allocation because other patients who are willing to accept transfusion would be seen as more likely to benefit from receiving the organ.

Rebuttal to Boggi and Colleagues

Boggi and colleagues' triage rationale for excluding a Jehovah's Witness patient for transplant listing should be rejected. While it is true that triaging a patient may incorporate a survival benefit as a factor governing allocation of resources, it would be unfair to apply it to our patient. In 2013, the Board of Directors of OPTN/UNOS approved changes to its kidney allocation criteria, which take survival benefit into account.[10] This policy was implemented after the patient in our case presented to the RMTI, and it would not have affected her eligibility to be listed. The aim of this new policy is to match kidneys that are expected to function the longest with patients whose life expectancy is longer, which would reduce the need for retransplant. This survival benefit criterion is ethically acceptable because it aims to optimize the distribution of kidneys based on sound evidence. Unlike this fine-grained policy, Boggi and colleagues' principle is a coarse calculation of whether a patient is more likely to die following transfusion-free transplant than another patient. It would not survive public vetting because its incompatibility with the empirical evidence on transfusion-free transplant makes it unacceptable.

Bramstedt's Rationale

Bramstedt's position is that organ loss must be prevented, when possible, because justice requires good stewardship of donated organs. As part of this stewardship, transplant teams must pro-actively address factors that contribute to organ loss. Bramstedt identifies noncompliance—when a patient fails to adhere to a prescribed treatment or medication—as one of the main culprits.[11] Within organ transplant practice, it is generally accepted that it is ethical for a transplant team to decide not to list a patient for transplant when the team does not believe the patient will comply with the lifelong antirejection medication regimen needed to ensure graft survival. Bramstedt claims that considerations of noncompliance can justify refusal of transplant to Jehovah's Witnesses because "if a patient refuses [peri]operative rescue transfusion, this puts the survival of the graft at risk."[12]

Bramstedt recommends that Jehovah's Witnesses be required to sign a rescue transfusion contract as a condition for receiving a cadaveric organ. She explicitly compares the case of an alcohol abuser and a Jehovah's Witness to support acceptance of blood transfusion as a condition for transplant. Many transplant centers require patients whose liver disease is caused by alcohol abuse to demonstrate six months of sobriety before listing them for transplant. Bramstedt's analogy appears to be that alcohol use by patients with alcohol-related liver disease and refusal of blood transfusion by Jehovah's Witnesses are alike because both are examples of noncompliance, and if a sobriety contract is a fair response, then a transfusion contract is also a fair response. If Bramstedt's analogy holds, then a transplant team would be justified in refusing to list our patient because she is noncompliant, which would allow the organ to be allocated to a patient who would be "compliant."

Rebuttal to Bramstedt

We agree with Bramstedt that noncompliance can be an ethical disqualification for receiving medical treatment, but we deny the grounds of her analogy: refusal to abstain from alcohol or refusal of blood transfusion are not similar to a refusal to comply with an antirejection medication regimen. Refusal to comply with an antirejection medication regimen is an example of noncompliance that sabotages the treatment, and compliance with antirejection medication regimen is a necessary condition for a successful organ transplant. Noncompliance is a more compelling reason to deny a patient a treatment when resources are scarce and a compliant patient will not be treated. Bramstedt's argument depends on a comparison to noncompliance, but the comparison is false.

Even if we accept that not remaining sober is an example of noncompliance, and an ethical basis for disqualification from transplant listing, refusal of blood transfusion is not enough like nonsobriety to disqualify a transplant candidate. This emphasis aims to prevent disease recurrence from renewed alcohol abuse, and the need for a subsequent retransplant. Our Jehovah's

Witness patient who requested a transfusion-free transplant poses no risk of future retransplant.

TRANSFUSION-FREE TRANSPLANT IN THE MEDICAL LITERATURE

Good medical ethics should reflect sound medical science. Physicians are trusted to be fair stewards of scarce medical resources, and their allocation decisions should incorporate principles of distributive justice and medical facts. Policy that excludes Jehovah's Witnesses who seek transfusion-free transplant from a transplant listing should have support in the medical literature. To determine whether the arguments made by Boggi and colleagues and by Bramstedt are supported by the literature, we searched PubMed for studies and reports on transfusion-free transplant. We discuss our findings below.

TABLE 1. Survival rates of Jehovah's Witnesses and matched cohort for transfusion-free organ transplant

	Jehovah's Witnesses (*N* = 13) %	Matched cohort (*N* = 25) %
Overall actuarial 3-year patient survival	83	80
Overall actuarial 3-year graft survival	66	77

Source: D.B. Kaufman et al., "A single-center experience of renal transplantation in thirteen Jehovah's Witnesses," *Transplantation* 45, no. 6 (1988): 1045-9.

TABLE 2. Survival rates for Jehovah's Witnesses and non-Jehovah's Witnesses for kidney transplant

	Jehovah's Witnesses %	Matched cohort %
1-year patient survival	87	97
5-year patient survival	72	81
10-year patient survival	51	60
1-year graft survival	82	87
15-year graft survival	67	61
10-year graft survival	43	18

Source: R. Kandaswamy et al., "Kidney and kidney/pancreas transplants in Jehovah's Witnesses—A single center experience with 50 transplants," *Acta Chirurgica Austriaca* 33, supp. 174 (2001): 3 (abstract 01), *http://doi.org/10.1007/BF02953431;*

Controlled Studies

There are two studies with controls about kidney and kidney-pancreas transplant in the literature. In 1988, Kaufman and colleagues published the results of their positive experience with kidney transplant for Jehovah's Witnesses, finding comparable success rates from Jehovah's Witnesses and non-Jehovah's Witnesses.[13] Kaufman and colleagues compared 13 Jehovah's Witnesses who underwent transfusion-free kidney transplant with a matched cohort of patients (n = 25) from the University of Minnesota (see table 1).

They found that the difference in actuarial and graft survival rates of the Jehovah's Witnesses and their counterparts were not statistically significant. And Kandaswamy and colleagues found no statistically significant difference in the one-to-10-year survival rates in this comparison of kidney transplant cases of Jehovah's Witnesses and non-Jehovah's Witnesses (see table 2).[14]

Case Reports

Alongside these studies, other transplant specialists have reported their experiences in kidney, kidney-pancreas, and liver transplant with their Jehovah's Witness patients. Our search of PubMed identified 14 case reports of transfusion-free transplant.[15]

The tentative conclusion that we draw from the two studies and the case reports is that there is no consensus in the literature that transfusion-free transplant poses a significantly greater risk of organ loss than transplant with transfusion. These studies and case reports reflect that medicine has embraced the challenge to develop surgical techniques that make transfusion-free transplant possible, and emphasize the importance of peri-operative care to successful transplants.

The Relevance of the Medical Literature

Review of the medical literature indicates that Boggi and colleagues' and Bramstedt's rec-

ommendations are not based on evidence. Given the two studies and positive case reports on transfusion-free transplant, Boggi and colleagues' proposal does not reflect an accurate assessment of the prospects for successful organ transplant. At worst, it presumes a difference where there is none. If the medical reasons that justify different allocations of resources for Jehovah's Witnesses are merely theoretical, the factor that disqualifies them from transplant listing requires vigorous scrutiny to determine whether the distinction is warranted and just. The medical profession must ensure it does not violate the principle of nonjudgmental regard when it limits patients' treatment options because of their religion.

Noncompliance may be an ethical disqualification from treatment when others are denied treatment. Bramstedt argues that the refusal of blood transfusion in organ transplant is such a case. The medical literature does not support this inference. It appears to indicate that Jehovah's Witness transplant recipients do as well as non-Jehovah's Witnesses. Bramstedt argues that failure to maintain sobriety and noncompliance with transfusion have similar effects on outcomes of graft survival. Multiple studies suggest that duration of sobriety prior to liver transplant is not a reliable predictor of abstinence following transplant.[16] A study by Rustad and colleagues suggests that it is possible to screen transplant candidates for potential alcohol relapse and aid the patients with targeted interventions.[17] Some transplant centers have revised their sobriety requirements to list patients with alcohol related liver disease for transplant.[18]

Having rebutted Boggi and colleagues' and Bramstedt's rationales for denying requests for transfusion-free transplant, we now consider an autonomy-based argument.

Respect for Autonomy?

Muramato has argued that the practice of "disassociation" imposes coercive pressure on Jehovah's Witness patients to comply with the Watchtower Society's guidance on blood transfusion, compromising the patients' autonomy to refuse it.[19] The implied argument is that physicians are not ethically obliged to honor a Witness patient's refusal of blood transfusion because the patient's refusal does not express an autonomous choice, and that a transplant team's imposition of consent to blood transfusion as a precondition for transplant listing does not violate the principle of respect for autonomy, since the patient's refusal of transfusion is seen as coerced.

Some healthcare professionals, like Muramato, may be reluctant to accept that honoring a Jehovah's Witness patient's refusal of blood transfusion is consistent with respect for the patient's autonomy. As Ridley noted, while medical staff may acknowledge that "honoring patient values in health care decision making and respecting patient self-determination are of the utmost importance," they may worry that a Jehovah's Witness has been psychologically manipulated to refuse blood transfusion.[20]

A Jehovah's Witness who accepts a blood transfusion is disassociated from the faith by his or her actions. Disassociated Jehovah's Witnesses are subject to communal shunning. The biblical justification for this is found in the apostle Paul's claim that Christians should "quit mixing in company" with persons who unrepentantly reject certain scriptural standards.[21] This is a flawed rationalization for excluding a faithful Jehovah's Witness from transplant listing. Although physicians may be tempted to judge that a Witness's refusal of blood transfusion is coerced, this would be a mistake. The practice of shunning may occur, but this is not sufficient grounds for physicians to determine that a Jehovah's Witness patient lacks the autonomy to make this decision. Shunning may have a coercive effect, but a policy that denies transplant listing to Jehovah's Witnesses who refuse transfusion due to this concern condemns them to die.

CAVEAT

We have argued that policies that reject Jehovah's Witnesses patients' requests for a transfusion-free transplant listing are unjust because they are conceptually flawed and not sufficiently sensitive to the evidence. Some may object that it is likely that allocating an organ to a Jehovah's Witness patient will increase inefficiency, at least incrementally, because some Jehovah's Witnesses will die during transplant or post-transplant. This is a possibility, but, in the absence of an empirically verified prognostic test for increased risk, it is unfair to prospectively deny a transplant listing to an individual Jehovah's Witness. The injustice of refusing to list a Jehovah's Witness is more significant than a

potential loss to marginal utility. Veatch has argued that justice is a moral principle that is independent of utility, that the superior ethic is one that prioritizes justice over utility, and that "no allocation formulation will be acceptable that is driven exclusively by utility."[22]

CONCLUSION

It is essential for decisions about listing Jehovah's Witnesses for transplant to take medical facts into account, if those decisions are to be ethical. As noted above, the medical consensus is that with proper peri-operative medical management and careful selection of candidates who are sufficiently healthy for transplant, the outcomes for Jehovah's Witnesses undergoing transfusion-free transplant are comparable to those of transplant patients who receive transfusions. The health of some Jehovah's Witnesses may make transplantation too risky, even with peri-operative optimization, and jeopardize the organ. In these cases it is fair not to allocate an organ, although transplant surgeons may offer it to a similar patient who consents to transfusion. Ultimately, reports of successful transfusion-free transplant in Jehovah's Witnesses are encouraging, and should expand access to treatment for these patients.

CLINICAL CASE RESOLUTION

The transplant surgeons at the RMTI believed that they could take peri-operative and operative steps to transplant the patient successfully, and because the patient was likely to die without a kidney transplant, she should be registered with OPTN for a kidney from either a hepatitis C positive or negative donor. The patient was listed for transplant in January 2014. The patient nearly received a kidney after three to four months on the OPTN registry, but another patient was a better match for the kidney. The patient also was notified of a possible match while visiting her daughter out of state, but was not able to come to the MSH due to inclement weather. Finally, a little over a year after registering with OPTN, the patient was matched to a kidney from a hepatitis C positive donor and underwent transplant. The patient continues to be monitored by the transplant team at RMTI, and she is doing well, soon to begin the new treatments for hepatitis C. When the patient reflects on her time waiting to be matched, she says that she was preparing to die, but Jehovah orchestrated the circumstances that allowed her to receive a kidney. "It would be devastating to have been denied the extra days free of dialysis to spend with my family."

ACKNOWLEDGMENTS

The authors wish to express their appreciation to Rosamond Rhodes, PhD, Mario Picozzi, MD, PhD, and Susan Lerner, MD, for their advice in preparing the manuscript that became this article. They also express their gratitude to the anonymous subject of the case for her generosity in sharing the details of her experience.

BLINDING OF THE CASE

Details of this case have been blinded to protect the privacy of the patient.

NOTES

1. D.A. Ott and D.A. Cooley, "Cardiovascular surgery in Jehovah's Witnesses: Report of 542 operations without blood transfusion," *Journal of the American Medical Association* 238, no. 12 (1977): 1256-8, doi.org/10.1001/jama.1977.03280130038011.

2. M. Introvigne and P. Zoccatelli, "Il pluralismo religioso italiano nel contesto postmoderno," 29 March 2017, *http://www.cesnur.com/il-pluralismo-religioso-italiano-nel-contesto-postmoderno-2/.*

3. "Immovable for the Right Worship," *Watchtower* 66, no. 13 7 July 1945): 195-204.

4. "Questions from Readers," *Watchtower* 88, no. 22 (15 November 1967): 702-4.

5. "Questions from Readers," *Watchtower* 110, no. 5 (1 March 1989): 30-1; "Questions from Readers," *Watchtower* 121, no. 12 (15 June 2000): 29-31.

6. "Questions from Readers," *Watchtower* 101, no. 6 (15 March 1980): 31.

7. U. Boggi et al., "Kidney and pancreas transplants in Jehovah's Witnesses: ethical and practical implications," *Transplantation Proceedings* 36, no. 3 (April 2004): 601-2, doi.org/10.1016/j.transproceed.2004.02.045; K.A. Bramstedt, "Transfusion contracts for Jehovah's Witnesses receiving organ transplants: ethical necessity or coercive pact?" *Journal of Medical Ethics* 32, no. 4 (April 2006): 193-5, doi.org/10.1136/jme.2005.012815.

8. Boggi et al., "Kidney and pancreas transplants," see note 7 above.

9. Ibid.

10. OPTN is the Organ Procurement and Transplantation Network, which operates under contract with the U.S. Department of Health and Human Services by the United Network for Organ Sharing (UNOS). UNOS is a nonprofit organization that manages the organ transplant system in the U.S.

"Board approves significant revisions to deceased donor kidney allocation policy—OPTN," Organ Procurement and Transplantation Network, 25 June 2013, *https://optn.transplant.hrsa.gov/news/board-approves-significant-revisions-to-deceased-donor-kidney-allocation-policy/.*

11. Bramstedt, "Transfusion contracts," see note 7 above.

12. Ibid.

13. D.B. Kaufman et al., "A single-center experience of renal transplantation in thirteen Jehovah's Witnesses," *Transplantation* 45, no. 6 (1988): 1045-9.

14. R. Kandaswamy et al., "Kidney and kidney/pancreas transplants in Jehovah's Witnesses—A single center experience with 50 transplants," *Acta Chirurgica Austriaca* 33, supp. 174 (2001): 3 (abstract 01), doi.org/10.1007/BF02953431

15. Ibid.; J. Figueiro et al., "Simultaneous pancreas-kidney transplantation in Jehovah's Witness patients," Clinical Transplantation 17, no. 2 (April 2003): 140-3; Boggi et al., "Kidney and pancreas transplants," see note 7 above, pp. 601-2; L.S. Hernández-Navarrete et al., "Experience in kidney transplantation without blood transfusion: kidney transplantation transfusion-free in Jehovah's Witnesses. First communication in Mexico," [title translated into English] *Cirugía Y Cirujanos* 81, no. 5 (2013): 450-3; P. Seu et al., "Liver transplantation for fulminant hepatic failure in a Jehovah's Witness," *Clinical Transplantation* 10, no. 5 (1996): 404-7; O. Detry et al., "Liver transplantation in a Jehovah's witness," *Lancet* 353, no. 9165 (1999): 1680; N. Jabbour et al., "Impact of a transfusion-free program on non-Jehovah's Witness patients undergoing liver transplantation," *Archives of Surgery* 141, no. 9 (2006): 913-7; American Liver Foundation, "More About Organ Donation," *http://www.liverfoundation.org/patients/organdonor/about/;* A. Stoye et al., "Bloodless liver transplantation in a Jehovah's Witness," *International Anesthesiology Clinics* 49, no. 2 (2011): 108-15, *http://doi.org/10.1097/AIA. 0b013e3181fa1482*; J.H.P. Garcia et al., "Liver transplantation in Jehovah's Witnesses patients in a center of northeastern Brazil," *Arquivos De Gastroenterologia* 50, no. 2 (2013): 138-140; G.P. Jeffrey et al., "Liver transplantation in Jehovah's Witness patients in Australasia," *Medical Journal of Australia* 187, no. 3 (2007): 188-9; J.Y. Jeong et al., "Liver transplantation in Jehovah's Witnesses: two cases report," *Korean Journal of Anesthesiology* 30, no. 3 (June 2017): 350-5, doi:10.4097/kjae. 2017.70.3.350; D.M. Brunetta et al., "Severe Acute Anemia After Liver Transplantation in an Elderly Jehovah's Witness Treated With High-dose Erythropoietin and Ferric Carboxymaltose: A Case Report," *Transplant Proceedings* 47, no. 8 (October 201): 2548-51, doi: 10.1016/j.transproceed; O. Detry et al., "Liver transplantation in Jehovah's witnesses," *Transplant International* 18, no. 8 (August 2005): 929-36.

16. A. Singvhi et al., "Ethical Considerations of Transplantation and Living Donation for Patients with Alcoholic Liver Disease," *AMA Journal of Ethics* 18, no. 2 (2016): 163-73, *http://journalofethics.ama-assn.org/2016/02/sect1-1602.html;* J.P. Rice and M.R. Lucey, "Should length of sobriety be a major determinant in liver transplant selection?" *Current Opinions in Organ Transplantation* 18, no. 3 (2013): 259-64; V. Donckier et al., "Ethical considerations regarding liver transplantation in patients with severe alcoholic hepatitis not responding to medical therapy," *Journal of Hepatolgy* 60, no. 4 (2014): 866-71.

17. J.K. Rustad et al., "Risk factors for alcohol relapse following orthotopic liver transplantation: A systematic review," *Psychosomatics* 56, no. 1 (2015): 21-35.

18. S. Bangaru et al., "Increased use of liver transplantation as therapeutic option for severe alcoholic hepatitis," *Digestive Disease Week,* June 2018, *https://cms.marketplace.org/sites/default/files/Sa1457%20-%20Increased%20use%20of%20liver%20transplantation%20as%20therapeutic% 20option%20for%20severe%20alcoholic% 20hepatitis.pdf;* R. Daswani et al., "Role of liver transplantation in severe alcoholic hepatitis," *Clinical and Molecular Hepatolology* 24, no. 1 (2018): 43-50, doi.org/10.3350/cmh.2017.0027; A. Margot et al., "Liver transplantation for alcoholic hepatitis: A systematic review with meta-analysis," *PLOS ONE* 13, no. 1 (2018), doi.org/10.1371/journal.pone.0190823*;* J. Lim et al., "Risk factors and outcomes associated with alcohol relapse after liver transplantation," *World Journal of Hepatology* 9, no. 17 (2017): 771-80.

19. O. Muramato, "Bioethics of the refusal of blood by Jehovah's Witnesses: Part 3. A proposal for a don't-ask-don't-tell policy," *Journal of Medical Ethics* 25, no. 6 (1999): 463-8.

20. D.T. Ridley, "Jehovah's Witnesses' refusal of blood: obedience to scripture and religious conscience," *Journal of Medical Ethics* 25, no. 6 (1999): 469-72.

21. "Questions from Readers," see note 6 above.

22. R.M. Veatch, "Equality, Justice, and Rightness in Allocating Health Care: A Response to James Childress," in *A Time to be Born and a Time to Die,* ed. B.S. Kogan (New York: Aldine De Gruyter, 1991), 205-16; R.M. Veatch and L.F. Ross, *Transplantation Ethics,* 2nd ed. (Washington, D.C.: Georgetown University Press, 2015). We are grateful to the anonymous reviewer who noted Veatch's view that utility is not superior to justice.

Cases from the Cleveland Clinic

Discomfort as a Catalyst: An Ethical Analysis of Donation after Cardiac Death in a Patient with Locked-In Syndrome

Bethany Bruno and Margot M. Eves

ABSTRACT

Donation after cardiac death (DCD) traditionally occurs in two patient populations: (1) those who do not meet neurological death criteria but who have suffered severe neurological damage, and (2) those who are fully alert and awake but are dependent on machines. This case highlights the unique dilemma when a patient falls between these two populations—conscious and cognitively intact, but completely paralyzed except for limited eye movement, afflicted by what the medical community refers to as locked-in syndrome. Prompted by the treatment team's discomfort, an ethics consultant examined whether the team was obligated to discuss a decision to donate with the patient, who was a registered organ donor. This article shows how, in determining whether or not to talk to the patient or family during end-of-life decision making, the weight assigned to the various ethical concerns in the case—the patient's condition, the decision to be made, and the family's agreement or disagreement regarding the patient's wishes—can "swing the pendulum" of ethical analysis in different ways. The comfort of the patient must be accorded the highest priority, as well as the needs of the patient's family. This case study highlights the nuanced contextual factors necessary to guide a treatment team's approach to DCD for a patient with uncertain decision-making capacity.

Bethany Bruno, BS, is a Medical Student at the Cleveland Clinic Lerner College of Medicine and is pursuing a Master of Arts in Bioethics at Case Western Reserve University in Cleveland, Ohio.

Margot M. Eves, JD, MA, is the Director of the Clinical Ethics Immersion Program and Staff in the Center for Bioethics at the Cleveland Clinic in Cleveland, Ohio. *evesm@ccf.org*

INTRODUCTION

In the United States, society strongly emphasizes the rights and privileges of the individual, with respect for patients' autonomy often held as paramount against other *prima facie* ethical principles. In this vein, healthcare professionals follow the voluntary decisions of patients who have decision-making capacity, or the decisions of surrogates who are acting in accordance with an incapacitated patient's wishes. However, this dichotomy is not always distinct, prompting the question of how to approach medical decision making when a patient's decision-making capacity remains unclear and the stakes are high, such as at the end of life. The emotional difficulty surrounding these situations affects discussions of beneficence and nonmaleficence, depending on the patient's views, cognitive ability, and current emotional state; such discussion might even be harmful to the patient. Nevertheless, when a family requests that healthcare providers not share a patient's

diagnosis with the patient—which is common in some cultures—healthcare professionals the U.S. are often uncomfortable with the idea of not talking to patients about their care, even when patients indicate that such discussions are unwanted. This article explores a case in which healthcare professionals felt such discomfort and were unsure whether to discuss withdrawal of treatment and organ donation after cardiac death (DCD) with a patient who had locked-in syndrome that was complicated by additional stroke impact and subsequent questionable cognitive ability.

CASE DESCRIPTION

Mr. Smith (not his real name) was a 62-year-old man with a history of heart failure who was admitted for difficulty breathing and seizure-like activity. Shortly after admission, he suffered a severe cardio-embolic stroke affecting the pons, midbrain, bilateral cerebellum, and left thalamus. Despite immediate intervention, emergent intra-arterial therapy failed to avert significant ischemic damage. At the time of the ethics consult, Mr. Smith had been diagnosed with locked-in syndrome; in locked-in syndrome, a patient is conscious and cognitively intact but completely paralyzed except for blinking and vertical eye movements. Since locked-in syndrome typically results from isolated pontine strokes,[1] it was possible that the patient had more deficits than just those traditionally seen in classic locked-in syndrome. Mr. Smith's condition limited a thorough evaluation of his understanding, especially given that sometimes he was awake and responsive but at other times he was unarousable, in a coma-like state. Given his extensive stroke burden, his condition was not expected to improve.

Mr. Smith had a large, highly involved family. His three daughters served as his surrogate decision makers, with the eldest acting as the primary spokesperson for the family. Worried about the diagnosis of heart failure, the patient had discussed his wishes with his children when he was conscious, and all of the children were confident that he would not want to live in a locked-in state, even though they said that they preferred that he try. During one of the patient's conscious intervals, his daughter confirmed her understanding of his wishes with him. A do-not-resuscitate (DNR) order was put in place until the decision to withdraw treatment was officially made during a family meeting, with the patient's daughters, multiple grandchildren, two sisters, and brother attending.

In accordance with hospital and organ procurement organization (OPO) policy, the OPO was notified of the patient's status prior to the family meeting, so the OPO might ask about donation after the conclusion of the end-of-life discussion. Before the OPO spoke to the family, they asked the healthcare team about organ donation. The patient was a registered organ donor and had previously spoken with his family about his desire to donate. However, caregivers and the OPO expressed discomfort about proceeding with DCD for a patient who appeared to be locked-in and therefore potentially cognitively intact.

An ethics consult was requested to address several concerns before the family meeting, including whether it would be beneficial to revisit the daughter's discussion with the patient, whether the team was obligated to review the decision to donate with the patient, and how to ensure the patient's comfort and minimize distress should the team proceed with DCD. From these concerns stemmed larger questions regarding when to talk with the patient versus the family when there is a question of capacity, what organ donor registration means, and what kind of experience we owe patients at the end of their lives.

DISCUSSION

Initial Discomfort

The thought of being trapped in one's own body, completely dependent on others and with limited ability to communicate with the outside world, often provokes a gut-wrenching reaction. For many, the thought of others making decisions about your care, including whether you live or die, without your input, is even worse. Tragic stories such as that of Rom Houben, who was inaccurately diagnosed as being in a persistent vegetative state for more than 20 years, lend further credence to this fear, and although Houben's story is extreme, reports suggest that the rate of misdiagnosis in disorders of consciousness is as high as 40 percent.[2]

Given these statistics, it is not difficult to understand why the medical team was uncomfortable with the thought of withdrawing life-sustaining treatment and carrying out DCD with-

out Mr. Smith's explicit consent. Even the OPO, which is generally prodonation, remained hesitant. Regardless of the difficulty in communication, if there was any chance that the patient was "in there," was there an ethical obligation to ask him what he wanted? Alternatively, was it ethically appropriate to rely on surrogate decision makers in this situation?

The Question of Consciousness

Intrinsic to this discomfort, and perhaps this case's most unique dilemma, is the question of consciousness and its significance. As reflected in the literature, discussions of treatment withdrawal and DCD, in general, occur in two distinct patient populations: (1) those who are not brain dead but who have suffered severe neurological damage and remain in an unconscious or minimally conscious state, and (2) those who are fully alert and awake but severely disabled and dependent on machines. In the first population, the patient must have previously provided consent by registering as an organ donor or the family must provide consent for treatment withdrawal and DCD. In the second population, the patient chooses to have life-sustaining measures withdrawn, thereby ending his or her life and subsequently donating an organ or organs. The latter situation is significantly rarer, with only several case reports published. In the U.S., these have primarily included patients with amyotrophic lateral sclerosis (ALS), commonly referred to as Lou Gehrig's disease.[3] There is at least one report from the Netherlands of DCD after euthanasia in a locked-in patient.[4] In these cases, the patients explicitly requested to end their lives through either discontinuation of life support or euthanasia and to subsequently donate their organs via DCD.

The case of Mr. Smith lies between these two extremes, and prompts the question of whether to talk to a patient or a patient's family when the patient's decision-making capacity remains unclear. Ultimately, the answer to this question is situation dependent, as the patient's condition, the decision to be made, and the family's agreement or disagreement regarding the patient's wishes may "swing the pendulum" of ethical analysis in different ways. As the gravity of the decision to be made increases, so does the drive to ascertain the patient's exact wishes; however, more difficult decisions necessitate a greater level of capacity on the part of the patient, which the patient's condition may, unfortunately, limit. Thus, in situations when a patient's capacity to make a decision is questionable, ethicists must weigh the value of getting the patient's input against the likelihood that he or she will be able to provide an informed decision. Whether there is consensus within the patient's family may tip the balance, for if there is widespread, unresolvable disagreement about what the patient would want, it may be worth at least trying to ask the patient directly, despite the question of capacity and, if necessary, over any objections by family members.

Nevertheless, ethicists should be wary of their motivation in asking patients with questionable capacity for their input. Honest reflection of motives must be made; in this case, ethicists must ask themselves whether asking the patient would be based on a sincere belief that the patient could provide a meaningful answer, or a desire to "check a box" and/or provide reassurance that the right course of action has been taken. This may not be possible to determine, but ethicists should, in any case, ask themselves these questions, and if they are primarily "checking a box," and this may do harm, they should consider omitting this step. Further, despite ethicists' best intentions, asking the patient for input can backfire. For example, if the patient fails to understand or cannot communicate, the discussion may contribute to the patient's frustration and angst, possibly causing psychological or emotional harm; or, if the patient makes statements contrary to his or her previously stated wishes, there is the additional challenge of trying to determine which stated wishes should be followed. Even though U.S. society places a strong emphasis on patients' autonomy, efforts should be made to avoid demanding a patient's input without a full consideration of the situation.

Ethical Analysis

In this context, the ethicist determined that the most ethically appropriate option was to forgo revisiting the conversation about withdrawing treatment with Mr. Smith. Given his waxing and waning responsiveness and the severity of his stroke beyond that of the typical locked-in patient, Mr. Smith's ability to comprehend the choices to be made remained unclear, even after the medical team's best assessment. Additionally, his large family was tightly knit

and appeared to react appropriately to their situation. They clearly applied the substituted judgment standard, honoring their understanding of the patient's wishes as they noted his desire not to live this way, despite their preference that he try to do so. These factors increased the ethicist's and the treatment team's comfort in relying on Mr. Smith's family members to make decisions; the ethicist's and team's comfort was further strengthened because the patient's daughter had discussed the patient's condition with him over the weekend. Given the difficulty of ascertaining the patient's ability to process information, the agreement among family members regarding what the patient's wishes were, and the conversation between the patient and his daughter that confirmed those wishes, the potential emotional harms of discussing end-of-life decisions outweighed the potential autonomy benefits of directly addressing the patient.

Similarly, from an ethical perspective, it was not necessary to review the decision to be an organ donor directly with Mr. Smith. Although the patient's condition was relatively uncommon, there is no substantive ethical difference in candidacy for DCD between a patient with locked-in syndrome and other potential DCD donors, such as a patient with ALS who is cognitively intact and desirous to discontinue life-sustaining support, or an unconscious or minimally conscious patient. Mr. Smith had previously chosen to register as an organ donor and had spoken with his family about his desire to be an organ donor, further indicating that donation was a value of his and was consistent with his wishes. To question his decision would be to hold him to a higher standard than that expected of other organ donors, whose donor registration would be respected without the corroboration of family members.

Although there remains variation in practice among OPOs, the 1987 amendment to the Uniform Anatomical Gift Act requires that a patient's donor registration be honored even when the family disagrees, out of respect for the patient's autonomy.[5] Furthermore, although individuals may change their donor status and choose not to donate at any time, to ask Mr. Smith in his state of questionable capacity about whether he would like to donate might have caused additional ambiguity or confusion if he then stated contradictory wishes. Putting all of this together, it was ethically supportable, and seemed preferable, to honor Mr. Smith's previously stated wishes by following the standard DCD process.

Although it was not ethically obligatory to confirm the decision to donate with Mr. Smith, the treatment team considered whether it would be reassuring to share with him that it would follow his wishes. Many patients and families find meaning and comfort in knowing that their loss will save others' lives through organ donation.[6] During these deliberations, the team discussed the uncertainty of DCD, as the process does not guarantee a patient's ability to donate. In order to proceed with the donation, the patient's heart must naturally stop within 60 minutes after life-sustaining support is withdrawn, to optimize the organs' viability for transplantation. Ultimately, this information was not shared with Mr. Smith, given concerns about his ability to understand and the emotional impact such a conversation might have on him. These are emotionally difficult topics that may be exacerbated by the potential for inadequate understanding of the information and the risk of conflating the questions of withdrawing treatment and donating organs. Depending on a patient's views, cognitive ability, and current emotional state, such discussion could even be cruel. It is unclear whether Mr. Smith's family discussed these plans with him. In retrospect, a better approach might have been to explore the family's thoughts on whether Mr. Smith would have found such knowledge reassuring, meaningful, or comforting, and, if they did, for the ethicist to support the family through the conversation. Without such family input, however, the potential comfort and other emotional benefits were not worth the risk of potential distress and other emotional harms.

Throughout the process, the ethicist and the treatment team remained attentive to the emotional needs of Mr. Smith's family. His youngest daughter was pregnant and appeared to be emotionally fragile in the setting of changing hormones, losing her father, and knowing her baby would never have a chance to meet his or her grandfather. Although these concerns were not relevant to the ethical analysis, they appropriately influenced the course of care. The team was careful to not prolong the end-of-life and donation processes, as each day waiting heightened the family's stress. At the same time, it was vital to ensure that the team's thought process and ethical analyses were not clouded by bias stemming from recognition of the national or-

gan shortage and their desire to promote organ donation.

In considering DCD for Mr. Smith, the team also raised questions about how to perform DCD in a manner that would ensure the patient's comfort and support his family. Following the institution's DCD protocol, Mr. Smith was transported to the operating room for implementation of comfort measures and withdrawal of life-sustaining measures, with his family accompanying him. The patient received all of the same comfort measures that would have been administered to any other patient in the intensive care unit (ICU) for whom life-sustaining treatment was withdrawn. The patient's comfort and pre-emptive pain management measures were accorded top priority, and the palliative medicine team ensured that Mr. Smith was sufficiently sedated and did not experience any distress, given that he had been intermittently alert and awake. Unfortunately, in that it precluded fully carrying out his wishes to donate his organs, Mr. Smith's heart did not stop within the requisite 60 minutes, and he was immediately taken back to the ICU to die peacefully, still with family by his side. Similar procedures should be followed in future cases regardless of the patient's level of consciousness.

Implications for Organ Donation Policy

Intrinsic to this ethics consult were questions of what organ donor registration means and how to assure a patient's comfort in the setting of DCD. With respect to the former, organ donor registration in the U.S. typically occurs at a state department of motor vehicles, but may also take place via online enrollment. However, these practices may limit an individual's autonomy by failing to assess the person's decision-making capacity, to ensure voluntary decision making that is free from external pressure, and to provide sufficient information about the risks and benefits of donation, to ensure an informed medical decision.[7] Despite this, in the U.S., society and the healthcare profession accept organ donor registration as a reflection of an individual's true wishes, and laws require that a patient's recorded wishes be followed.[8] Nevertheless, recognition of these limitations gave this treatment team pause in considering Mr. Smith, given the possibility, however remote, of potentially revisiting the decision to donate with him—an opportunity that is never available to donors who meet death by neurological criteria, and is rarely available to DCD donors. For the previously discussed reasons, this avenue was ultimately not followed, but the question did highlight the failures of our organ donor registration system. Although solving this problem is outside the scope of this article, if all individuals who completed organ donation registrations did so with voluntary, informed consent, with full decision-making capacity, there would be no need to question an individual's donor registration status, whether nonresponsive or awake.

CONCLUSION

Mr. Smith was afflicted by locked-in syndrome and had questionable cognition and waxing and waning of consciousness. His case demonstrates the need for a careful balance between respect for autonomy and beneficence. Although not discussing the patient's wishes with him initially elicited discomfort among team members, further analysis indicated that it was not ethically obligatory to review his decision to donate, but rather that it was ethically supportable to honor his previously stated wishes by following the standard DCD process. In future cases, the question of whether to talk to a patient or a family when a patient's decision-making capacity is unclear may differ depending on the patient's condition, the decision to be made, and the family's agreement or disagreement regarding the patient's wishes. This case demonstrates the importance of access to a robust and trusted ethics consultation service and a treatment team's willingness to pause for reflection on and assurance of the ethical supportability of an organ donation plan. It also highlights the benefit of having pre-emptive discussions and an advanced directive to facilitate end-of-life care that aligns with a patient's wishes.

BLINDING OF THE CASE

Details of the case have been altered to protect the privacy of the patient's family members.

NOTES

1. E. Smith and M. Delargy, "Locked-in Syndrome," *BMJ* 330, no. 7488 (February 2005): 406-9.

2. L.S.M. Johnson, "The Silent Scream: Misdiagnosis in Disorders of Consciousness," (Hasting Center Bioethics Forum Essay) *Health and Health Care*

(11 December 2009), *https://www.thehastingscenter.org/the-silent-scream-misdiagnosis-in-disorders-of-consciousness/.*

3. T. Smith et al., "Organ Donation after Cardiac Death with Withdrawal of Life Support in Patients with Amyotrophic Lateral Sclerosis," *Journal of Palliative Medicine* 15, no. 1 (2012): 16-9; S. Toossi et al., "Organ Donation after Cardiac Death in Amyotrophic Lateral Sclerosis," *Annals of Neurology* 71, no. 2 (2012): 154-6.

4. O. Detry et al., "Organ Donation after Physician-Assisted Death," *Transplant International* 21, no. 9 (August 2008): 915.

5. Uniform Law Commission, National Conference of Commissioners on Uniform State Laws, "Anatomical Gift Act (2006)," *http://www.uniformlaws.org/ActSummary.aspx?title=Anatomical%20Gift%20Act%.20(2006)*

6. N. Hogan, M. Coolican, and L. Schmidt, "Making Meaning in the Legacy of Tissue Donation for Donor Families," *Progress in Transplantation* 23, no. 2 (June 2013): 180-7; A. Ralph et al., "Family Perspectives on Deceased Organ Donation: Thematic Synthesis of Qualitative Studies," *American Journal of Transplantation* 14, no. 4 (April 2014): 923-35.

7. J. Bester and J. Gross, "Organ Donor Registration Reconsidered: How Current Practices Strain Autonomy," *American Journal of Bioethics* 16, no. 11 (November 2016): 33-5.

8. Uniform Law Commission, National Conference of Commissioners on Uniform State Laws, "Anatomical Gift Act (2006)," see note 6 above.

Perspective

To Give or Not to Give: The Challenge of Pharmaceutical Coupons

Mihail Zilbermint and Louise Schiavone

ABSTRACT

Diabetes is epidemic and many people cannot afford insulin, a lifesaving medication, as its price has increased by almost 160 percent in the past five years.[1] To help subsidize the cost of insulin, one of the staff members at my hospital would like to give patients copayment coupons provided to her by pharmaceutical companies. I advised my colleague to stop distributing these branded coupons, as they promote particular pharmaceutical companies. This practice is not consistent with the policy on interaction with industry established by the Johns Hopkins Health System. Yet at the same time, I want my patients to be able to afford their insulin so they can treat their diabetes. I truly believe in utilitarianism. Would temporarily subsidizing patients' insulin make me and my staff better healthcare providers? Would this minimize my patients' financial burden? Would giving away medications coupons help pharmaceutical companies influence me as a prescriber? This challenge created a personal internal debate and profound moral distress.

Mihail Zilbermint, MD, is an Assistant Professor of Medicine in the Division of Endocrinology, Diabetes, and Metabolism at the Johns Hopkins University School of Medicine in Baltimore, Maryland; is Chief of Endocrinology, Diabetes, and Metabolism at Suburban Hospital in Bethesda, Maryland; is Director of Endocrinology, Diabetes, and Metabolism at the Johns Hopkins Community Physicians at Suburban Hospital in Bethesda; and is a Student at Johns Hopkins Carey Business School in Baltimore. *mzilber3@ jhmi.edu*

Louise Schiavone, MS, is Senior Lecturer with a specialty in communications at Johns Hopkins Carey Business School.

INTRODUCTION

Insulin is a lifesaving medication for patients with diabetes mellitus. After insulin was discovered and purified in Canada in 1921 by Frederick Banting, Charles H. Best, and James B. Collip, the patent was sold for only $3 to the University of Toronto.[2] They hoped that affordable insulin would soon cure diabetes around the world. The price of major insulins such as glargine (Lantus) and detemir (Levemir) pens increased by at least 160 percent in the past five years, according to a 2015 *Bloomberg Health* report.[3] Today, a box of insulin glargine pens (typically one month's supply) costs up to $400, which makes it unaffordable for many people in the United States, particularly those who do not have health insurance.[4] It is reasonable to assume that any cost-saving opportunity would be greatly appreciated by patients.

The pharmaceutical industry is playing a "prescription teaser game" by distributing branded medication coupons and samples to doctors' offices that enable patients to save anywhere between $20 and $400 on insulin, but only if they select their brand product.

One of the staff members at my hospital would like to give away copayment coupons, provided by pharmaceutical companies. This individual's reasoning is this: "[I] worry that it does a disservice to our patients not to help them with medication costs and copays. . . . We are simply helping our patients out by enabling them to get their medication, which is prescribed without [their careproviders'] input, and the end result hopefully would be that at least for 30 days (hopefully longer), this patient won't be readmitted because he/she could not afford medication to keep them out of the hospital." However, receiving coupons or samples from pharmaceutical companies is forbidden by a Johns Hopkins Medicine Policy on Interaction with Industry.[5] This conflict presents a moral conundrum.

MORAL ANALYSIS

Would temporarily subsidizing patients' insulin make me and my staff better healthcare providers? Would this minimize my patients' financial burden? Would giving away medication coupons help pharmaceutical companies influence me as a prescriber?

As a caring physician, my ultimate goal is to help patients by "doing whatever I can." Helping patients afford their expensive medications is one goal of the treatment plan, since there is little point in prescribing a medication that patients cannot afford. The Johns Hopkins Policy on Interaction with Industry states, "The practice of accepting free pharmaceutical samples risks interference with one's prescribing practices since industry representatives often provide the newest and most costly drugs. Therefore, free pharmaceutical samples and vouchers for free pharmaceutical samples may not be accepted."[6]

My personal intuitive moral judgment is complex. Human life is the most important value involved in this case. On the first day of my medical school, the dean of the university introduced us to the Latin phrase *Aliis inserviendo consumor,* "Consumed in the service of others," which rapidly became my motto. This is where my own values and moral judgments conflict.

This may be a classic right/wrong conflict. Rightfully, I want my patients to receive the best treatment and care. At the same time I understand that pharmaceutical companies are simply employing the concept of "reciprocity," one of the most powerful influence weapons as described by Robert Cialdini.[7] After receiving something for free, Cialdini maintains, doctors feel obliged to prescribe that particular medication more often, creating a damaging conflict of interest. When patients receive medication coupons, they often come back for a refill. Doctors prefer not to change insulin brands too often. Then the end result is that these patients, who first received the subsidized insulin, ultimately pay the full price later, thus benefiting the pharmaceutical company that issued a coupon.

MAJOR STAKEHOLDERS

There are three major groups of stakeholders in this moral dilemma: patients, industry, medical staff. Patients with diabetes obviously need treatment (insulin). And who doesn't like "freebies" and "an opportunity to save a buck or two?" as one of my patients recently described it. Medical providers want "the best for their patients," and if this particular brand of insulin is available with a subsidy, then it probably should be prescribed. Often physicians themselves are unaware that they are being influenced.[8] Finally, the pharmaceutical industry is interested in marketing and selling their product with an ultimate goal of increasing revenue and benefiting their own stakeholders.

In this article, we focus on the drug industry in light of a business's corporate responsibility to create shared value. I concede that the pharmaceutical industry invests millions of dollars in research and development of new drugs and formulations, and the companies would like to maximize their return on investment. However, basic medications, such as insulin, should be almost free, and certainly, in general, inexpensive because they are necessary to save lives. The industry must have its own moral compass to create opportunities for the uninsured to obtain their medications, especially for those who have a limited income.[9] Fortunately, a number of big-name pharmaceutical companies already provide services that benefit society, and not just the company . For example, AstraZeneca helped to provide training and awareness to increase breast-cancer treatment in Kenya.[10]

Importantly, Johns Hopkins Health System has established a Johns Hopkins Medicine Outpatient Medication Assistance Program to "meet the short term needs of uninsured clinic patients who had previously relied on industry samples

for their medications."[11] Under this program, uninsured patients may receive up to a 30-day supply of selected medications at a limited number of locations. In the case of my hospital, the closest participating pharmacy is in Columbia, Maryland, nearly 30 miles away. Another initiative, Mobile Medical Care, is a designated Federally Qualified Health Center, based in Maryland and a close partner of my hospital.[12] It is a network of primary care and specialty clinics that serve low-income and uninsured residents of Montgomery County, Maryland. Once patients enroll in the MobileMed network, they receive medical consultations, labs, and medication for a modest flat fee ($25 to $80, based on a sliding fee scale). Unfortunately, due to the cumbersome logistics, including travel and paperwork, it is not enough for our patients.

OPTIONS AND DECISIONS

Options are limited. I can instruct my staff to continue giving away insulin copay vouchers, by pretending that "I am not doing it, they are," and justifying it by saying that "We are doing what is right for the patient, which is paramount." Alternatively, I may misinterpret the policy by admitting that "Doctors are not allowed to take the prescription vouchers from pharmaceutical companies," but "there is nothing wrong if you give those coupons away." I may justify "an exception," by stating that "transitional benefit may overweight the risks," assuming a patient cannot easily afford the drug now. Finally, I can suggest that my staff stop giving away coupons and prescribe older generic insulin (which costs significantly less.) I picked the latter option, citing the conflict of interests and the policy.[13] These industry marketing materials do influence doctors' prescribing behavior, despite repeated denials. I feel that distributing coupons may help a few dozen patients pay for their insulin this month, however this may influence their opinions and may hurt other patients in the future. I choose to prescribe cheaper generic insulin to uninsured patients. However, there is a similar moral problem with this choice since I feel obliged to tell them which pharmacy has the cheapest insulin (that is, large discount retail chains), thus unintentionally advertising another industry.

Other medical fields may experience similar challenges. For example, some hospitals and birth centers distribute branded infant formula discharge packs to breast-feeding mothers in the United States, although this practice has recently declined.[14] This marketing campaign by infant formula manufacturers may imply that hospital and medical staff endorse a particular formula brand.[15]

Dilemmas remain. To the extent that it is the physician's imperative to "first do no harm," one must ask, where is the greatest harm done: in failing to provide free, albeit promotional, medication to financially stressed patients? Is drawing patients to higher priced medication, first offered for free, a kind of "bait and switch"?

All of this, of course, does not even address the often-heard charge that the drug, medical, and foods industries are working together to take away all incentives for Americans to improve their habits and lose weight, causing an increase in U.S. healthcare spending.[16] For example, a recent report found that annual diabetes spending between 1996 and 2013 was $64.4 billion, with $44.4 billion of this increase spent on pharmaceuticals.[17]

SUMMARY

Prescribers should avoid accepting samples and gifts from pharmaceutical companies, since it may compromise their independent judgment and even promote nonrational prescribing behavior.[18] Healthcare policy makers should work together with the industry to make lifesaving medications available and affordable.[19]

ACKNOWLEDGMENT

The authors thank Diane Cooper, MSLS, NIH Library, for assistance in writing this article. The authors thank Sherita H. Golden, MD, for reviewing this article.

NOTES

1. R. Langreth, B. Migliozzi, and G. Kataki, "The U.S. Pays a Lot More for Top Drugs Than Other Countries," 18 December 2015, *https://www.bloomberg.com/graphics/2015-drug-prices/.*

2. C. Idlebrook, "Selling a Lifetime of Insulin for $3," *https://insulinnation.com/treatment/medicine-drugs/selling-lifetime-insulin/.*

3. Langreth, Migliozzi, and Kataki, "The U.S. Pays a Lot More," see note 1 above.

4. M.R. Page, "Insulin Pens: Improving Adherence and Reducing Costs," *Pharmacy Times*, 19 May 2015, *https://www.pharmacytimes.com/publications/directions-in-pharmacy/2015/may2015/insulin-pens-*

improving-adherence-and-reducing-costs.

5. "Johns Hopkins Medicine Policy on Interaction with Industry: Pharmaceutical Samples," section 2.d., *https://www.hopkinsmedicine.org/research/resources/offices-policies/OPC/Policy_Industry_ Interaction/policy_ interaction_industry.html.* Section 2.d. went into effect 1 July 2011.

6. Ibid.

7. R.B. Cialdini, *Influence: Science and Practice,* 5th ed. (Boston: Pearson Education, 2009).

8. P. Komesaroff, "Doctors' Interactions with the Pharmaceutical Industry: Science or Commerce?" *Internal Medicine Journal* 31, no. 8 (November 2001): 446-7.

9. L.J. Thompson, "The Global Moral Compass for Business Leaders," *Journal of Business Ethics* 93, no. 1 (1 June 2010): 15-32.

10. M. Sebastien, "What Is the Social Value of Pharmaceuticals?" 13 February 2014, *https://www.fsg.org/blog/what-social-value-pharmaceuticals.*

11. "Johns Hopkins Medicine Outpatient Medication Assistance Program," 13 August 2015, *https://www. hopkinsmedicine.org/research/resources/offices-policies/OPC/Policy_Industry_Interaction/jhm_outpatient_medication_assistance_ program. html.*

12. Mobile Medical Care, *http://mobile medicalcare. org/.*

13. Johns Hopkins Medicine, "Johns Hopkins Medical Policy," see note 5 above.

14. J.M. Nelson, R. Li, and C.G. Perrine, "Trends of US Hospitals Distributing Infant Formula Packs to Breastfeeding Mothers, 2007 to 2013," *Pediatrics* 135, no. 6 (June 2015): 1051-6.

15. K.D. Rosenberg, C.A. Eastham, L.J. Kasehagen, and A.P. Sandoval, "Marketing Infant Formula through Hospitals: The Impact of Commercial Hospital Discharge Packs on Breastfeeding," *American Journal of Public Health* 98, no. 2 (February 2008): 290-5.

16. J.L. Dieleman et al., "Factors Associated with Increases in US Health Care Spending, 1996-2013," *Journal of the American Medical Association* 318, no. 17 (2017): 1668-78.

17. Ibid.

18. M. Kessel, "Restoring the Pharmaceutical Industry's Reputation," *Nature Biotechnology* 32, no. 10 (2014): 983-90.

19. M.A. Morgan et al., "Interactions of Doctors with the Pharmaceutical Industry," *Journal of Medical Ethics* 32, no. 10 (October 2006): 559-63.