

Virtual Mentor
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Problematizing the Principle of Autonomy

From the Editor

Clinical Responsibility in the Age of Patient Autonomy 567
Barbara Chubak

Educating for Professionalism

Clinical Cases

**Deciding for Others: Limitations of Advance Directives,
Substituted Judgment, and Best Interest** 571
Commentary by Ryan E. Lawrence and Daniel J. Brauner

**Dilemmas in End-of-Life Decision Making for the Medical
Tourist Patient** 582
Commentary by Malika Haque and Hafzah Mueenuddin

**Communicating Risk of Infertility to Adolescents Prior
to Chemotherapy** 589
Commentary by John Hutter and James L. Klosky

On Call

Patient Autonomy and Physician Responsibility 598
Commentary by Patrick C. Beeman and Ryan C. VanWoerkom

Medical Education

**Tethered to the Diving Bell: Beyond Vulnerability
to Autonomy** 603
Denise M. Dudzinski

Teaching Physician Decision Making in a Technical Age 607
David Segal and Richard L. Fernandez

Journal Discussion	
The Belmont Report’s Misleading Conception of Autonomy	611
Sigurdur Kristinsson	

Clinical Pearl	
Prognosis and Therapy after Cardiac Arrest-Induced Coma	617
Megan Alcauskas	

Law, Policy, and Society

Health Law	
Donors Retain No Rights to Donated Tissue	621
Kristin E. Schleiter	

Policy Forum	
Autonomy and Exception from Informed-Consent Research	626
Catriona Macardle and Rachel Stanley	

Medicine and Society	
How Autonomous Is Medical Decision Making?	631
Andrew Fagan	

Resources

Suggested Readings and Resources	636
About the Contributors	645

Upcoming Issues of *Virtual Mentor*

September: Ethical Questions in Genetic Testing
October: Religion, Patients, and Medical Ethics
November: Medical Education Reform
December: HIV Care and Ethics

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FROM THE EDITOR

Clinical Responsibility in the Age of Patient Autonomy

The *Principles of Biomedical Ethics* by Thomas Beauchamp and James Childress, arguably the foundational text of contemporary bioethics, was first published in 1979 at the close of a decade that witnessed the rise of the international patients' rights movement [1]. In the United States, this movement placed, and continues to place, a particular emphasis on individual choice, in keeping with the dominant political ethos of our nation, which since its conception has privileged the enlightened, rational, and productive individual actor. Out of these ideas, the principle of respect for autonomy was born, and, since then, the influence of this single principle on the provision of health care and conduct of biomedical research has eclipsed that of the other principles: beneficence, nonmaleficence, and justice.

The reasons for this are more than just historical. Justice, while an important and admirable goal, is by definition relational, requiring equity between two or more equals. Because of this quality, it is of limited relevance in clinical encounters where the focus is on a single patient; it is only in aggregate that patient experiences can be considered through the lens of justice. Beneficence and nonmaleficence, the oldest and best-established obligations of the physician, suffer from the opposite problem, insofar as they can only be reliably defined by a single person for himself. What is good or bad, beneficial or harmful, is so profoundly subjective that any attempt to stand by these principles forces the question: who decides? The principle of autonomy has been our medical system's attempt at providing an answer.

The autonomy principle reminds us that every individual person has values, reasons, and standards of his or her own, as well as an interest in self-determination. It tells us that medicine must be practiced so that an individual's self-determination is protected, and he or she is empowered to make medical decisions according to those personal values, reasons, and standards. Usually, this requirement is couched in terms of individuals' autonomy rights, echoing the more overtly political discourse of patients' rights. In theory, this right to autonomy would be universal, but philosophers are fond of saying, "ought implies can," and some are incapable of exercising their autonomy due to either temporary or permanent decisional incapacity. Absent the ability to articulate a reasoned choice, we do not recognize a patient as having autonomy.

It is with this point that the August 2009 issue of *Virtual Mentor* begins, with the case of a patient whose advance directive is being contested by his family. In his commentary, Ryan E. Lawrence describes how we use surrogates as patient alternates when the patient is unable to exercise autonomy, offering a critique of the

interpretive openness of advance directives. Interestingly, Lawrence explains the purpose of advance directives as “respecting patient wishes and preserving autonomy,” treating these two goals as synonymous. Daniel J. Brauner begins by suggesting that the patient be included in discussions of his medical care, regardless of whether he is capable of decision making, as a measure of respect for him as a person. Ultimately, Brauner recommends a time-limited trial of the therapy desired by the patient’s surrogate decision makers, which he describes as a “palatable choice” for patients and their families. There are certainly good medical reasons for imposing a time limit on patient care. If the surrogates disagree with the limited trial, however, the physician essentially exercises a veto power over their autonomous decision making.

The second case calls attention to the degree to which the definition and importance of autonomy are culturally contingent. As I have noted, autonomy in American bioethics is rooted in Enlightenment philosophy and political theory, which are the products of a specific historical and geographic milieu. Is it appropriate to impose our ideas about autonomy on individuals who do not share our geographic origins or identify with our history? In her commentary about a Muslim man who comes to the United States for treatment, Malika Haque points out the variety of prevalent ideas about religion and gender in different Muslim nations and among individuals. Interestingly, even as she argues that physicians ought to respect their patients’ religious beliefs and seek expert assistance in order to accommodate their values, Haque’s conclusion advances an interpretation of Islam and women’s medical decision making that is at once authentic and yet very different from the patient’s sons’ in the case she is discussing—and presumably from the patient’s also. Similarly, Hafzah Mueenuddin suggests that common ground between the patient’s family and his physician might be found in their shared commitments to the good of the community and to the preservation of communal resources, even though the communities to which these actors are committed are, in fact, very different.

The clinical pearl by Megan Alcauskas complements this clinical case by explaining that an important role for the neurosurgeon who is treating someone in a coma is to offer the patient’s family the best available prognostic information as a basis for their decision making.

The third case touches upon a classic controversy in pediatrics—should older adolescent patients be empowered to make autonomous medical decisions? John Hutter’s commentary reveals how physicians are bound by both law and tradition not to grant full consent power to patients who, made vulnerable by both youth and disease, have a particular need for the protection that is the promise and purpose of the autonomy principle. In contrast with Hutter’s pragmatic conservatism, James L. Klosky’s commentary invites us to deviate from established practice, stating that all oncologists have a responsibility to discuss infertility risk with patients—including adolescents—during their reproductive years. He offers advice on how to empower adolescent patients to make their own medical decisions but suggests that helping the patient’s parents communicate with their son may be the best approach.

In the on call section, medical student Patrick C. Beeman describes a case in which a patient with an iatrogenic hematoma subsequent to a cardiac catheterization procedure wishes to remain hospitalized longer than his physicians deem necessary. We discover that, in this case of “dueling autonomies,” the patient remained hospitalized for 14 days.

The particular irony of most approaches to respecting patient autonomy is made clear by Denise M. Dudzinski in her discussion of *The Diving Bell and the Butterfly*, which she uses in her role as a bioethics educator to teach medical residents about the principle of autonomy. Dudzinski explains that it is through vulnerability, by recognizing, accepting, and incorporating human frailty and incapacity into our clinical care, that we come to a true understanding of what autonomy means. The locked-in experience of author Jean-Dominique Bauby suggests that in practice autonomy is not something that one automatically has, but rather something that we give to each other through respectful personal interaction. This radical idea poses a stark contrast to traditional thinking about autonomy, which considers it a right inherent in the human condition, even though it is not possessed by all humanity.

In their policy forum article describing the relationship of autonomy to exception from informed consent (EFIC) research, Catriona Macardle and Rachel Stanley reach a conclusion that is similar to Dudzinski’s, arguing that the subjects of EFIC research do not have any substantive autonomy to lose, not because of youth or lack of decision-making capacity, but rather due to the emergency room environment and its inability to accommodate the social interplay that true autonomy requires. Macardle and Stanley note that the lack of informed consent in EFIC human subject research has been maligned by some as a controversial violation of individual autonomy. Sigurdur Kristinsson follows with a thoughtful analysis of the Belmont Report, explaining that its emphasis on informed consent to respect patient self-determination fails to protect human research subjects. Only a deeper understanding of autonomy—the patient’s and the researcher’s—accomplishes that protection.

The health law article by Kristen E. Schleiter recounts cases that have delineated the limits of autonomy over one’s body. Schleiter explains how, in each legal decision, the social good represented by research won out over the individual’s claim to sovereignty over detached parts of his or her body. Thus, we see again how, in practice, autonomy is less a right that inheres in one’s person than a product of what one is granted through social interaction—in this case the interactions of the court. It is because of this invented quality of autonomy, which ultimately seems built less on principle than on people, that the interactive medical teaching tool described by David Segal holds such promise as a way of understanding the complexity of autonomy in practice.

In his compelling and controversial medicine and society piece, Andrew Fagan goes beyond Schleiter’s argument to suggest that autonomy has psychological, as well as somatic and cognitive limitations. He maintains that, along with the ability to

articulate one's reasoned opinion, the ability to choose freely among available options is an essential part of what it means to be an autonomous medical decision maker and that this ability is far more rare than is commonly assumed. Focusing on the religious and moral beliefs that are foundational to the communal, familial, and educational structures in which we are raised, Fagan suggests that these structures so limit our freedom to choose among values as to make the practice of autonomy impossible.

Regardless of whether we have the freedom to choose our most fundamental beliefs or whether we are doomed to play out the game of life with the cards that we are dealt, we do decide whether, when, and how to play. Ultimately, the articles in this issue invite us to think, act, and choose in ways that are respectful of the needs, feelings, and even the unfree beliefs of others. Perhaps it is by emphasizing this choice, rather than any problematic autonomy right, that we will find our best way forward.

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CLINICAL CASE

Deciding for Others: Limitations of Advance Directives, Substituted Judgment, and Best Interest

Commentary by Ryan E. Lawrence, MDiv, and Daniel J. Brauner, MD

Mr. Abbot was taken to the local hospital from the nursing home where he had lived since his dementia became too severe for him to be unsupervised for any length of time. At 70, his health had been good, enabling him to enjoy the amenities of the nursing facility, stroll on the grounds, participate in art and music therapy, and visit with family and pets on a weekly basis. He was admitted to the hospital with a diagnosis of pneumonia and was in respiratory distress, which was likely to require intubation.

Years prior, before losing decision-making capacity, Mr. Abbot had documented in his advance directive that if he ever became demented and was unable to recognize his family or friends, he would prefer that no attempts be made to resuscitate him, should it ever be necessary. Mr. Abbot's family, which included three children, made no effort to hide this directive, which was in his medical record, but insisted that it should not be acted upon. The children explained to the doctor that, despite his compromised cognition, their father was currently enjoying his day-to-day life in the nursing home, and should be intubated.

Commentary 1

by Ryan E. Lawrence, MDiv

When patients cannot make their own decisions it is often difficult to know how to proceed. One approach, described by Allan Buchanan and Dan Brock in their book, *Deciding For Others*, is to employ a hierarchy of principles [1]. First and foremost, decision makers should consider any directives the patient articulated when competent. The second-line approach is substituted judgment, wherein those who know the patient best carry out the course they think the patient would have chosen were he competent. If these options cannot be employed, decision makers may act on what they believe is in the patient's best interest. This hierarchical approach has been highly influential in medical ethics, but it has limitations that are visible in the case provided. These shortcomings are the focus of this commentary, which aims to discern how applicable Buchanan and Brock's paradigm is to this and similar situations involving patients who are no longer competent.

Advance Directives

Respect for patient autonomy is often the dominant principle in medical ethics and, according to some, in all of medicine [2, 3]. Arguably, following advance directives

provides the best means of respecting the patient's wishes and preserving autonomy when the patient no longer has decision-making capacity. Most patients (76.5 percent in one survey) expect their wishes to be carried out in the event that they cannot make decisions for themselves [4]. Therefore, few would disagree that advance directives have a strong *prima facie* weight—overlooking them requires serious justification.

Even if all parties agree with using advance directives to respect patient autonomy, many decision makers still face difficult questions about what interventions and situations are covered by the directive. In the present case, Mr. Abbot said he would not want resuscitation but did not specify what forms of resuscitation he would not want. Fluid resuscitation is rather benign; chest compressions are not, and intubation may not even count as resuscitation—many hospitals separate “do not resuscitate” (DNR) from “do not intubate” (DNI) when specifying goals of care.

Alzheimer's dementia affects persons gradually, allowing for good days and bad days. Would Mr. Abbot's advance directive take effect on the first “bad” day on which he did not recognize a family member, or did he intend to wait until he no longer had good days? Difficulties in discerning a patient's intended meaning limit the usefulness of advance directives.

Moreover, a strict application of an advance directive may not reflect the patient's autonomous choice in its entirety. Patients often harbor misunderstandings about the interventions they are choosing or rejecting and even the implications of *having* advance directives [5]. Physicians, too, may misinterpret the patient's wishes. A case report described one nursing-home resident who was said to be DNR, based on his living will, but after developing a gastrointestinal bleed and being taken to the hospital, he told the doctors that he was *not* DNR, adding, “I know I am an old man, but if the condition is treatable, I would like the chance to be treated” [6].

Patients may also place varying emphasis on their autonomy. In a 2005 study by Thorevska and colleagues, most patients (59 percent) created their living wills in consultation with a family member [5]. Similarly, Mazur and colleagues reported that most patients (62.5 percent) preferred shared decision-making models involving their physicians over solely patient-based approaches (preferred by 15.5 percent) [7]. Those who include others while formulating their advance directives may well want to include others in the implementation of those directives. Thus, strictly applying advance directives may not do justice to all of the patient's wishes.

Substituted Judgment

The second-line approach, substituted judgment, generally does not overrule advance directives, but may play a role when questions emerge about how to interpret and apply advance directives. In the present case, substituted judgment might be important when considering whether Mr. Abbot's instructions would have changed had he known the details of his present situation: his happy existence despite Alzheimer's, the acute course of his pneumonia, and his family's unified desire for a

short-term trial of intubation. Yet, limitations of the substituted judgment principle also emerge when it is applied here.

Because of Mr. Abbot's medical condition, his true wishes cannot be known, so there is no objective way of determining whether his family's judgment is a true substitute for his. The family's decision to override the plain reading of his advance directive suggests that they may be merely substituting their own preferences under the guise of "substituted judgment." Following the advance directive, however, would leave questions about whether the family gave adequate weight to important details the patient did not anticipate (his happy existence, his medical condition, and his family's wishes).

Shortcomings of substituted judgment are not limited to the present case, but affect the principle more broadly. In one study, medical students could accurately describe substituted judgment but made important mistakes when applying it; if doctors struggle to apply the principle correctly, surrogates might have even more difficulty [8]. When testing the approach, proxy decision makers using substituted judgment were correct only 70 percent of the time [9]. Moreover, patient preferences change over time, making it difficult to anticipate what a patient will choose. In one study, 10 percent of survey respondents who did not want mechanical ventilation in 1999 had changed their minds 3 years later [10]. On the whole, evidence suggests that substituted judgment can be difficult to understand and apply, making it an unreliable means of preserving patient autonomy.

Best Interest

The last option in Buchanan and Brock's paradigm, the principle of best interest, likewise has limitations. In the present situation, Mr. Abbot's best interest is debatable. Generally, patients' best interest involves having their autonomy respected and their rights of self-determination protected—which would push decision makers in this case toward following the advance directive. Yet it is not in a patient's best interest to have prior instructions misinterpreted or applied in ways the patient did not intend. Furthermore, many patients would not consider it in their best interest to create conflict for their families. These observations rightly make clinicians cautious about implementing the advance directive under the banner of serving the patient's best interest.

Another tempting approach, invoking a patient's *medical* best interest as grounds for dismissing an advance directive, is problematic when the patient's future course is unclear. In one study of elderly patients with severe pneumonia, researchers observed a 40 percent mortality rate among those who required intensive care (87 percent of all study patients were intubated). Furthermore, survivors spent 15.6 days on average in the ICU [11]. A cognitively impaired patient might find this experience bewildering and distressing, to the say the least, and might still die in the end. There is also no guarantee that the patient would return to baseline health status following the illness. A study of nursing-home residents with dementia found that, 3 months after a lower respiratory infection, 21 percent had a decline in functional

status (33.2 percent were dead, 45.8 percent were alive with no decline) [12]. Overall these odds are not bad; they just might not be good enough to justify violating an advance directive. These data also highlight that, while it is tempting to frame the question as one of choosing life or death for the patient, the real question is whether or not to choose aggressive treatment. Medical uncertainties temper enthusiasm for acting unilaterally on behalf of the patient's best interest.

Often it is not clear which path best serves a patient's interest, medical or otherwise, for it is difficult to know which of the patient's interests should be given priority and at what cost to the other interests. This does not preclude decision makers from discussing the patient's best interest, but it does suggest that the principle is not a simple or unfailing rule for making complex medical decisions.

Leaving the Principles Aside

Advance directives, substituted judgment, and best interest all have limitations that constrain their usefulness when making medical decisions for patients who cannot choose for themselves. Awareness of these limitations allows us to shift attention to other observations that may provide guidance when patients cannot make their own decisions.

First, when the patient cannot make his own decisions, someone else must make them in his behalf. This point is itself controversial; some believe that surrogates who merely report a patient's prior wishes are not making genuine decisions [13]. Surrogates at no point abdicate their role as decision makers, since, even when the patient's wishes have been expressed previously, the surrogates still make crucial interpretive decisions about when and how to implement those stated wishes. In the present case, unless the physician, the state, or some other designated party steps in and decides how to interpret and implement Mr. Abbot's advance directive, the family retains some latitude in deciding whether his advance directive will apply.

Second, those who make medical decisions for incompetent patients may, and indeed must, consider factors beyond patient autonomy and advance directives. In an era dominated by autonomy, this point is rarely explicitly made but does have some supporters. A recent survey found that many U.S. physicians do not exclusively hold a patient's expressed wishes as their highest concern when making ethically complex medical decisions [14]. Likewise Jonsen, Siegler, and Winslade advocate that physicians consider all the facts of a case in order to arrive at a more balanced judgment [15]. In this context, the family is permitted to consider factors other than the patient's advance directive.

Finally, in light of these observations, refusing to implement an advance directive does not necessarily disrespect the patient. This is particularly true when there are questions about the applicability of advance directives or when additional information exists that probably would have influenced the patient's decision.

In the present case, the family should be allowed to offer the final verdict on whether to intubate Mr. Abbot. The physician can make an extra effort to educate the family about the pros and cons of each possible decision and about current theories in medical ethics, but the physician should not forbid intubation based on the patient's advance directive. (Incidentally, these arguments also allow room for physicians to challenge patients' advance directives on occasion. How to resolve physician-family disagreements over patient care is a separate question that warrants its own commentary.) Hierarchical decision-making paradigms such as that offered by Buchanan and Brock may be helpful at times, but when they create more ethical ambiguity than they resolve, it is appropriate to set them aside.

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Commentary 2

by Daniel J. Brauner, MD

In the preceding case commentary, Ryan E. Lawrence presents a spot-on portrayal of the principle-based paradigm in 21st century North America for making end-of-life medical decisions for those who are unable to speak directly for themselves. He then sets the paradigm aside, in favor of allowing the family to make decisions with input from the physician because of the ethical ambiguity inherent in applying principles of autonomy articulated in advance directives to an actual medical situation. This phenomenon is repeated countless times in similar situations and closely reflects the reality of modern medical decision making.

Many aspects of Mr. Abbot's case deserve mention, including the assumption of his lack of decision-making capacity due to the extent of his cognitive impairment—an assumption that needs to be grounded in some attempt to include him in discussion of his medical care [1]. Even finding that Mr. Abbot lacks decision-making capacity does not necessarily mean that his voice should not be part of the decision-making discourse along with those of his family and doctors [2].

Some time ago, Stephen Post and others raised the question that this case asks: should we honor the wishes of the “then” (precedent autonomous) self or the “present” self in persons who are transformed by their dementia [3]. In this regard, it is important to consider why recognition of family members stands as such a watershed moment for Mr. Abbot and so many other patients with dementia. Failures of recognition usually make a greater difference for family caregivers, who understandably become distressed when the person with whom they shared so much no longer recognizes them. National and local context also plays a role. If Mr. Abbot lived in Holland, for example, a country rated highly in its care to the elderly, and was a nursing-home resident, he would most likely not be transferred to the hospital,

regardless of his family's preferences, and intubation and CPR would not be options [4]. This forces us to ask whether a person with dementia who resides in a nursing home should have his or her care options limited compared to a person with the same degree of problems who is able to continue living at home because of better resources.

Exploration of the Language of Advance Directives

To better understand the case of Mr. Abbot and others like him, it is helpful to explore the history and evolution of advance directives, recognize why they fail to help us to make decisions, and encourage a rethinking of current practice. Although it is not explicitly stated in the scenario, the advance directive that Mr. Abbot signed was in all probability a DNR order to take effect in the future when his dementia had progressed to the point that he did not recognize family members. It is the question of whether to order a DNR that often frames discussion about the future and is stated here as Mr. Abbot's desire that "no attempts be made to resuscitate him." As Lawrence points out in his commentary, the meaning of resuscitation is not entirely clear. The DNR order was the first codified limitation of therapy, and it ushered in a revolution in end-of-life care by providing important options for gravely ill and dying patients. The way DNR is currently used in end-of-life discourse, however, has become an obstruction to clear communication and good care.

Asking every patient who might die—ultimately all patients—whether he or she wants to be resuscitated has become standard practice in the United States and is generally thought of as a marker of good end-of-life care. In its latest incarnation as a central component of the goals-of-care conversation, the question is usually introduced when a patient's prognosis is grave and doctors have run out of what they consider reasonable chances of successful curative therapy. The DNR order of the 1970s was a logical response to what can now be recognized as a failed experiment, begun early in the history of the modern age of resuscitation with the notion that everyone who died would first be in cardiac arrest and should therefore undergo resuscitation. This was a radical shift from prior practice.

Prior to this shift, as noted in *A Manual on Cardiac Resuscitation* published in 1954, the indication for resuscitation procedure was "cardiac arrest or stoppage of the heart in the operating room," most commonly from a catastrophic reaction to anesthesia [5]. Until 1960, cardiac resuscitation involved the application of open-cardiac massage to a limited number of patients, usually via thorocotomy and almost exclusively in the operating room. But in response to the high success rate with the first 20 patients to be resuscitated using closed-chest compressions (70 percent survival), reported in 1960, the study authors decided to take their technique to the rest of the hospital and explicitly changed the definition of cardiac arrest [6]:

Cardiac Arrest is [now] the sudden and unexpected cessation from whatever cause of circulation producing cardiac activity. *This term once applied only to the sudden death associated with anesthesia and surgery* [7].

Within a very short time, despite the much grimmer success rate of chest compressions when more generally applied, and without any widely vetted public policy debate, cardiac arrest became accepted as a new stage in the human experience of dying, and cardio-pulmonary resuscitation (CPR) became the universal default for all patients in cardiac arrest in the hospital [8].

A cascade of ensuing forces then led to the development of the “order not to resuscitate” (ONTR) in 1974, followed most significantly in 1976 by a mandate that patients or their families be allowed to make this decision [9]. These changes arose because the early expectations of dramatically altering life expectancy were dashed by CPR’s lack of efficacy in the vast majority of patients to whom it was applied. The escalating public debate about the ambiguous value of many life-prolonging therapies and the growing patients’ rights movement reached a climax with the Quinlan decision in 1976, which authorized the first publicly acknowledged removal of ventilatory life support in a person who was still alive [10].

The Quinlan decision set the stage for open discussions about actually limiting treatment, as heralded by an editorial in the *New England Journal of Medicine*, “Terminating Life Support: Out of the Closet” [11]. One of the papers in this series was precedent-setting in its call for the active participation of the patient and family in deciding whether or not to forgo CPR [12]. The idea of giving patients and families ultimate choice was again supported by the President’s 1983 Ethics Commission, which suggested that the concept of futility was inherently too uncertain to allow for the creation of “clear and workable categories” for limiting CPR [13].

Legacy of Cardiac Arrest and DNR

Although much has changed in the past 30 years, the case of Mr. Abbot shows that much has also stayed the same. The repercussions of the establishment of cardiac arrest as the liminal state between life and death and the subsequent DNR order for withholding CPR still echo in our present-day conversations with patients and families. The choice of whether or not to perform CPR was the first specific, mandated decision in which patients and families were explicitly given a voice in determining their care. As such the “code” discussion served as an early prototype for decision making with patients and families. It is still often used as a point of entry to talk about future care, both with gravely ill patients in the hospital and, as in Mr. Abbot’s case, with healthy individuals when considering the more distant future.

Physicians can use the advance-directive frame or code discussion as a barometer to gauge desired intensity of care. In some circumstances, physicians will go beyond the question of code status to discuss with patients exactly what level of aggressiveness they want, ranging from everything except CPR to various other possible limitations. This practice is further reinforced by the use of “partial DNR” orders, in which patients and surrogates choose from a menu of options parsed out from the CPR protocol, including intubation, cardioversion, compressions, and use of antiarrhythmic and vasopressor drugs. Over time, these choices have been

expanded to include procedures that are not necessarily related to resuscitation, but to more general advance care planning, such as the use of artificial hydration and nutrition. The DNR discussion can thus serve as a springboard for other aspects of care.

The great irony of this legacy is that the CPR procedure, which stimulates all of this discourse, will most likely not be effective in significantly altering the outcome of the illness or process from which most of us will die. (Of course, there are many conditions related to acute, sometimes iatrogenic events that are reversible by CPR/advanced cardiac life support (ACLS) and deserve its rapid application.) Nevertheless, in homage to the history of resuscitation, cardiac arrest, DNR, and the spirit of patient autonomy, we are left with a ritualized discussion that compels physicians to offer a therapy which will most likely be ineffective.

Recommendations

From the perspective gained through this historical review, let's get back to Mr. Abbot. He had chosen DNR in the event his dementia became intolerable to his "then" self. This is a reasonable choice, especially in a nursing home, where the rate of successful resuscitation is even lower than in the hospital and where some have advocated to not even offer CPR [14]. We may also be justified in assuming that his DNR order signifies "then" Mr. Abbot's desire for less-aggressive therapy in general [15]. But the DNR tells us little about what he would want now, and assumptions about aggressiveness based on a DNR order are nebulous. Ever more detailed advance directives based on the flawed cardiac arrest model have not yielded significant improvements [16-18].

There are several decision points that make more sense than DNR in contemplating Mr. Abbot's situation. The "do not hospitalize" order functions as a much more powerful advance directive and can be applied to nursing-home residents who have reached a point in their disease trajectory where the burden of hospitalization overwhelms the potential benefit it offers [19]. Once Mr. Abbot is in the hospital, the decision to intubate for impending respiratory failure must be clearly differentiated from the intubation performed as part of CPR/ACLS. Elective intubation for impending respiratory failure associated with a potentially reversible condition like pneumonia, although fraught with higher rates of morbidity and potential mortality for Mr. Abbot than for a younger, healthier patient, as Lawrence points out, is a life-saving procedure in the majority of patients in a study he cites. A time-limited trial of intubation with aggressive antibiotic treatment for pneumonia is often a quite palatable choice for older patients who share the understandable dread of spending the last days of their life in a prolonged death on a ventilator.

This time-limited trial would be the choice I would offer to the family if Mr. Abbot is not able to be involved in the decision. It appears that they are making decisions based on his best interest and his current, quite decent quality of life and want him to be treated if there is a reasonable chance of his returning to that life. If, after a reasonable time, the duration of which should be clearly stipulated beforehand, he

does not appear to be improving, he would be extubated. Aggressive palliative care should be part of his treatment during his entire hospitalization, with special considerations if he is extubated because of lack of improvement. Of note, if he is extubated because of lack of response, when his heart stops he should not be considered to be in cardiac arrest but dying, and CPR would not be indicated.

Of course, to follow the procedure that I advise would require some conceptual and bureaucratic changes, but perhaps it is time for us to move beyond the current paradigm.

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Virtual Mentor

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CLINICAL CASE

Dilemmas in End-of-Life Decision Making for the Medical Tourist Patient

Commentary by Malika Haque, MD, and Hafzah Mueenuddin, JD

Mr. Abdullah had just been admitted to the ICU at a major academic medical center. He had traveled there to undergo surgery recommended by his doctor back home in Damascus, Syria. Shortly after his arrival, Mr. Abdullah suffered a heart attack and went into cardiac arrest. His son, who had accompanied him on the trip, called 911, and Mr. Abdullah received CPR for 18 minutes on the way to the hospital. Although his pulse returned, Mr. Abdullah was breathing on a ventilator and comatose on exam.

Neither Mr. Abdullah nor his son spoke English, so Dr. Kramer, the ICU physician, communicated through an interpreter. She explained what had occurred and ordered a neurology consult to evaluate the degree of hypoxic-ischemic injury to his brain and determine whether he was likely to regain consciousness. The consult concluded that Mr. Abdullah was unlikely to regain any significant neurological function.

During their conversation about Mr. Abdullah's prognosis, Dr. Kramer stated that there was a risk that he might code again and advised that a DNR order be written. Mr. Abdullah's son agreed that this was appropriate, and the order was written. The following day, however, the son asked that the DNR order be rescinded, saying that he had spoken with his older brother back in Syria and that his brother, who stood at the head of the family in their father's stead, thought the DNR was inappropriate. Confused by this sudden reversal, Dr. Kramer asked if any other family members had weighed in with their opinions. The son replied that they had not, nor had they been asked to; he and his elder brother were their father's only sons, and the feelings of their mother and sisters were irrelevant in this case.

"In fact," the son explained through the interpreter, "our mother has not been told about what has happened to our father since his arrival because my brother did not wish to upset her."

Dr. Kramer knew from previous experience that, by law, if a patient had not designated someone to exercise power of attorney for health care, the responsibility for decision making on the patient's behalf fell first to his wife. If he had no wife or if she declined to act as surrogate, then it fell to the majority decision of adult children. She explained this legal requirement to Mr. Abdullah's son and asked him to help her act accordingly. The son refused, upset by the doctor's apparent disrespect for his culture.

Commentary 1

by Malika Haque, MD

Proper case management of Mr. Abdullah, a Muslim patient from Damascus, Syria, who has suffered a severe hypoxic brain injury requires the services of several experts to ensure the best possible care for him and his family. Barriers to good care include language, culture, and religious differences and the physical distance that separates Mr. Abdullah from most of his family members. The services of a qualified interpreter are needed, as is the guidance of a physician who is knowledgeable in Islam and Islamic medical ethics. Finally, the assistance of an Islamic religious leader such as an Imam or an Islamic scholar will help achieve an outcome with which everyone involved can feel comfortable.

Since the patient is Muslim, Islamic law and Islamic medical ethics are important governing factors in decision making. Islamic law is derived from the Qur'an, the Muslim holy book, and from the Hadiths, the traditions of the Prophet Muhammad (peace be upon him). Islamic medical ethics is based on Islamic law as well as statements of Islamic scholars. The Ethics Committee of the Islamic Medical Association of North America (IMANA) offers clarification in the management of patients and has published a position paper that covers many medical and ethical dilemmas [1].

In this particular case, the prognosis for neurological recovery is poor. If Mr. Abdullah survives, he is unlikely to recover neurologically and will remain in a persistent vegetative state (PVS). IMANA does not endorse prolonging the misery of a patient who is dying of a terminal illness when death is inevitable or of a patient in a PVS. In such cases, IMANA's position is that the patient should be allowed to die without unnecessary procedures while at the same time receiving nutrition, hydration, antibiotic treatments, and palliative care [2, 3]. No additional attempts should be made to sustain life with artificial life support. If the patient is on mechanical support, this can be withdrawn with the consent of the patient's family members [1-4]. IMANA is, however, opposed to euthanasia and assisted suicide [2]. Initiating a DNR order is appropriate for Mr. Abdullah, according to IMANA's position [2-4]. IMANA also recommends that all Muslim patients have a living will and an advance directive to assist physicians in understanding the wishes of patients who are in situations akin to that of Mr. Abdullah [1].

One strategy for overcoming these language, culture, religion, and physical distance barriers is to call on the services of an Imam or Islamic religious leader or scholar. Although Muslims are a diverse group of people with many different cultures and languages, they share universal respect for the knowledge and guidance of an Imam. The Imam's expertise along with the physician's medical explanations would be most effective in conveying the patient's status in Islamic terms to the family in the United States and the family overseas. In this case, for instance, an Imam could help the family understand that initiating a DNR order does not mean their decision resulted in Mr. Abdullah's death. The spiritual implications that accompany a

family's DNR decision for a loved one can be addressed by the Imam in religious terms. He can explain that accountability for the loved one's death does not rest on the shoulders of family members who do not request futile attempts at sustaining their loved one's life. The Imam can help family members understand that *letting go* does not equal responsibility for Mr. Abdullah's death.

Another matter of concern in managing this particular patient appears to be the role of gender in Islam. The Qur'an at 2:187 states that men and women are each others' garments or each others' protection [5]. Muslim women have the right to marry men of their choice, divorce, obtain education, spend their earnings as they wish, and raise their family with their husband's support. The equal status of the sexes is not only recognized, but insisted upon. The Qur'an at 3:195 cites that any good deed done by a male or female is never wasted, for one is the offspring of the other [6]. Independent and strong Muslim women are not foreign concepts in Islam. In fact, Khadija, the first wife of the Prophet Muhammad (peace be upon him), was a wealthy business woman who proposed to Muhammad (peace be upon him) and lived happily with him until her death at the age of 65. Khadija was the first person to accept Islam after it was revealed to her by Prophet Muhammad (peace be upon him) [7]. This example of an independent and strong woman in Islam is reflected doctrinally in the right of women to make decisions mentioned above.

Despite many examples of the equal status of women in Islam, various cultures label Muslim women as weak and lacking the strength to make important decisions—particularly decisions about life and death. Such notions are culturally based, arising from the beliefs that prevail in the woman's country of origin as well as the level of education the woman had obtained.

Pakistan, Indonesia, and Bangladesh all have had Muslim women as heads of state. Many Muslim women are also highly educated and succeed in the professional ranks while assuming the traditional roles of wife and mother. Prophet Muhammad (peace be upon him) has stated that paradise lies under the mother's feet—indicating the great respect due to mothers in Islam [8].

In this case, Mr. Abdullah's wife is the most appropriate figure to make a decision regarding her husband's life. Her sons seem to be protective of their mother and do not think it necessary to burden her with such a difficult decision. Perhaps they do not think she is strong enough to hear difficult news or decide upon the DNR order. Here, the Imam or an Islamic scholar can assist in conveying the difficult news to the patient's wife, but with or without an Imam's help, Mr. Abdullah's wife should have been informed and given the opportunity to decide upon the DNR order.

This particular case reflects several medical, cultural, and ethical issues that must be handled by a team of experts. The use of a physician knowledgeable in Islam and Islamic medical ethics is preferred, an interpreter should be employed, and an Imam or religious leader who can effectively communicate with the family will be most helpful.

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Commentary 2

by Hafzah Mueenuddin, JD

As medical tourism becomes more common, whether due to complicated medical conditions or economic incentives, patients and physicians are quickly finding they are exchanging more than a fee for specialized medical services. Often, cultural constructs of autonomy and surrogate decision making are also being exchanged. Customs and laws that guide surrogate or proxy decision making have a significant impact on many traveling patients. In the following discussion, I explore how legal and cultural constructs of autonomy and surrogate decision making complicate Mr. Abdullah's care.

Addressing Legal Requirements with Family Members

Many approaches could have been taken when Mr. Abdullah's son refused to contact his mother, Mr. Abdullah's wife. Evidence requirements for establishing patients' wishes vary by state, as does the hierarchy of people who can make medical decisions for a patient who lacks capacity to decide. Most states place the patient's spouse at the top of the hierarchy for surrogate decision making, followed by the patient's children. In the present case, this means that the medical team would first refer its questions to Mr. Abdullah's wife (who is not present). The medical team is

legally obligated to make a good faith effort to contact the first person in the hierarchy of decision makers. If it is difficult to contact the patient's spouse, the team may discuss his medical condition with his children. But Mr. Abdullah's wife should be given the opportunity to accept responsibility for making these decisions or to pass it on to other family members.

Because Mr. Abdullah's son is worried about how his mother may take the news, Dr. Kramer will need to adjust her approach to discussing Mr. Abdullah's condition with her. Dr. Kramer may simply state that she is calling to determine whether Mrs. Abdullah would like to make decisions regarding her husband's medical care if he becomes unable to do so. Should Mrs. Abdullah agree to make medical decisions for her husband, the team will have to include her in all decisions requiring consent. Dr. Kramer should further state that Mrs. Abdullah is not required by law to accept the responsibility; she can choose to forgo being her husband's surrogate decision maker, in which case the responsibility will shift to her children. Alternatively, Mrs. Abdullah may appoint a person she feels is trustworthy and more knowledgeable about what her husband would want and someone who is in a better position to make medical decisions for him. This would allow the medical team to fulfill its legal responsibility of affording Mrs. Abdullah an opportunity to accept or refuse decision-making responsibility and may allow family members to continue to provide for Mrs. Abdullah's comfort in the best way they know.

Another option is to present the situation to a multidisciplinary group, which may support Mr. Abdullah's son and open novel ways of discussing options and decisions for his care. In this case, it would be helpful to ask an Imam to discuss how Islamic law and culture interpret the patient's medical condition. The Imam would be able to explain that U.S. law offers an opportunity for Mr. Abdullah's wishes to be heard from those who know him best. Involving the patient's spouse in medical treatment decisions by no means shows disrespect, but rather enables the patient's autonomous wishes to be heard from a trustworthy source (here, his wife). One 2002 study showed that medical teams in the ICU found involvement of religious scholars and extended family extremely important in helping Muslim decision makers cope with their responsibilities [1]. In this case, Dr. Kramer should stress that she hopes to gather more information about Mr. Abdullah and create family support for his son in the United States.

Addressing DNR Status in the Islamic Context

Another important concern for the physician and patient is Mr. Abdullah's DNR status. Before a decision about resuscitation can be made, medical benefit must be clearly defined and agreed upon by Dr. Kramer and Mr. Abdullah's family. In this instance, it may be that Mr. Abdullah's condition could become more painful and difficult if he were resuscitated, and, in Dr. Kramer's view, resuscitation may offer Mr. Abdullah no benefit while prolonging his life in a state of greater suffering. By contrast, Mr. Abdullah's family might view resuscitation as a chance at "life." Because physicians, patients, and families may interpret the "benefit" of treatment in vastly different ways, discussing these views and the reasons behind them with

patients (when possible) and families is extremely important. In general, Islam views withholding treatment as morally permissible where physicians determine that continued aggressive treatment is not providing any medical benefit [2]. This is because delaying the patient's death with continued life-sustaining treatment is not in the patient's or the community's best interest [2]. The prolonging of life, in Islam, is not as important as the quality (moral and otherwise) of the life lived [3].

Another option Dr. Kramer has if she feels very strongly that a DNR order is best for Mr. Abdullah is stating that she will institute the DNR order after enough time has passed to allow (1) an independent physician in the hospital to evaluate Mr. Abdullah's condition to determine if DNR status is necessary, or (2) the family to make arrangements to move Mr. Abdullah to another hospital or let him return home. In most states, physicians may institute a DNR order after informing the family of these options. Nonetheless, to continue strengthening the relationship with the family, decision makers, and the medical team, it is important to inform all parties involved in the patient's medical care of changes in treatment plans or goals and provide them an opportunity to voice their opinions.

Autonomy and the Muslim Patient

Islam values autonomy and free will as unique characteristics of humankind, but respect for autonomy is often eclipsed by the greater importance of family and community, inasmuch as an individual's welfare is intimately linked with that of his or her family's [2]. This differs significantly from the Western or American concept of autonomy and individual liberties. Hence, while American patients or families may feel they have a right to demand treatment options as an exercise of their autonomy, Muslim patients are likely to take a broader view shaped by input from external sources such as family and community. Muslim patients and families are more likely to understand that limiting use of resources on one individual may contribute to the greater good. This is not simply a recognition of the medical constraints of one's community, it also recognizes an overarching responsibility toward preserving the welfare of one's community resources. In Mr. Abdullah's case, appealing to this sense of familial and communal good both in reaching out to his wife and in discussing his DNR status will help his son and family understand the centrality of these points of view and help them place decision making in a context they understand.

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CLINICAL CASE

Communicating Risk of Infertility to Adolescents Prior to Chemotherapy

Commentary by John Hutter, MD, and James L. Klosky, PhD

Andrew, 13, was recently diagnosed with acute myelogenous leukemia (AML). At his second appointment with the pediatric oncologist he and his parents were told about the standard induction treatment for AML: chemotherapy with a combination of anthracycline and cytarabine. The oncologist, Dr. Kessler, described the various side-effects of this course of treatment, including infertility. Andrew and his parents understood, and, after asking a few questions about scheduling, they agreed to start chemotherapy as soon as possible.

Later, while Andrew was out of the room, Dr. Kessler told his parents that if Andrew banked some sperm prior to the initiation of chemotherapy he would be able to have biological children in the future, in the event that his sperm became infertile secondary to his chemotherapy. She explained that banking sperm was a fairly simple procedure, requiring only that Andrew masturbate to produce the semen from which the sperm would be extracted to be frozen and stored. There was a banking facility nearby, which she could contact if Andrew's parents were interested in learning more about the process. She asked their permission to speak with Andrew about the risks and benefits of sperm banking.

To Dr. Kessler's surprise, Andrew's parents not only refused their permission, but reacted to her proposal with horror. "We've worked hard to raise our son to be a good boy who would never think about doing anything as inappropriate and immoral as masturbation," said Andrew's father. "Yes," his wife agreed, "suggesting to Andrew that he masturbate would upset him, so we insist that you not say anything about this to him. He has accepted that he might be infertile after this treatment is finished; let's just leave it like that, and hope for the best." Dr. Kessler agreed, and the appointment came to an end.

Commentary 1

by John Hutter, MD

In responding to the queries posed by this scenario, it is essential to consider the importance of context in applying ethical principles. The concept that context is part of ethical decision making dates back to Aristotle's *Nichomachean Ethics* and means simply that what is right under certain circumstances might be wrong when circumstances differ. Let's begin by exploring aspects of this scenario that define its context.

Andrew is newly diagnosed with acute myelogenous leukemia, a life-threatening malignancy requiring immediate treatment. If the proposed sperm-banking procedure were to delay antileukemia treatment, Andrew would be at greater risk than a patient with a newly diagnosed malignancy that posed less immediate danger.

A second contextual consideration is the universality of the proposed sperm-banking intervention. Is this a procedure that is routinely and consistently performed for all newly diagnosed adolescents with cancer? While banking of sperm has been strongly recommended for adolescent males about to undergo therapy that may affect fertility, a substantial number of adolescent male cancer patients do *not* undergo the procedure prior to the institution of therapy. Sperm banking is not routinely employed for various reasons, including, as I mentioned, the immediacy of required anticancer therapy, lack of emphasis on fertility preservation in oncology training programs, and procedure costs, which often place an additional burden on families. The lack of universal application of the proposed procedure lends support to the argument that parental consent be required for a minor undergoing this intervention, even if the intervention were both desired by the minor patient and potentially of some benefit.

A third context factor is Andrew's pubertal development and ability to provide an ejaculate sperm sample. Although not specifically stated, let's assume that his physician had established that Andrew had sufficient pubertal development and ejaculate capabilities to carry out the banking procedure. This factor, albeit obvious, is a good example of the context concept, i.e., what's right to propose to a pubertal adolescent about sperm banking may not be appropriate for a prepubescent child. Similarly, Andrew's age and stage of development should be considered; approaches to early adolescents may differ from those proposed to adolescents more advanced in their cognitive and emotional development.

The risk for Andrew in declining sperm banking also requires evaluation [1]. The overall risk of azoospermia following chemotherapy treatment of adolescents and young men has been best studied in Hodgkin's disease. Azoospermia rates as high as 90 percent have been observed after multiple cycles of chemotherapy that includes alkylating agents, but declines to 30 to 50 percent when patients receive three cycles or fewer of chemotherapy or are treated with regimens that do not include an alkylating agent.

Factors that influence the risk of infertility after chemotherapy include the age and sex of the patient, type of chemotherapeutic agent, and dose intensity. Younger patients generally have a lower risk of infertility than older individuals. Males have a slightly greater risk of infertility than females who receive an identical treatment regimen. It is difficult to apply fertility-risk data to current therapies because many of the treatment regimens for which the fertility outcomes have been calculated have been supplanted by newer regimens with improved cancer survival outcomes. Hence, exact risk of infertility from the regimen proposed for treatment of Andrew's acute

myelogenous leukemia (anthracycline and cytarabine) remains incompletely defined but might carry a lower risk than treatment regimens that include alkylating agents.

Most likely, Andrew will remain capable of sperm production after a single chemotherapy cycle with anthracycline and cytarabine, but several small studies have suggested there is an increased risk of transient aneuploidy of sperm following chemotherapy administration. In considering a recommendation for Andrew prior to the initiation of chemotherapy, one must also take into account that sperm motility in leukemia patients may be lower than normal prior to treatment. Disease-related decreased sperm motility, when combined with the urgent need for treatment that may preclude obtaining multiple samples for banking, and Andrew's age (13 years) increase the possibility that the sample obtained will not be adequate in both sperm numbers and function. Studies of successfully banked sperm, however, demonstrate that adolescents with cancer have the same sperm DNA viability as normal controls.

Decision Making in Stressful Times

The diagnosis of a life-threatening illness in a child or adolescent is extremely stressful for a family. Parents are faced with a situation that is out of their control and may also feel that they did something wrong that contributed to the illness. A high level of stress may influence the parents' responses to the sperm-banking recommendations. Treating oncologists should appreciate how their own inherent beliefs about what is in the patient's best interest can influence their acceptance of a parental response. For example, would one's opinion about Dr. Kessler's acceptance of Andrew's parents' decision be altered if the parents had said, "We are refusing sperm banking because we appreciate the urgency of commencing chemotherapy and don't want to risk any delays"? While we might find the latter response less disquieting and more acceptable because it is more consistent with the context of our own beliefs, the response still generates the same end result—namely a parental request to exclude Andrew from a medical decision-making process.

Adolescent Assent

A key question posed by the scenario is the degree to which we respect adolescent autonomy in medical treatment choices, which has implications for ethical decision making, constitutional rights of individuals, and legal policy making. When does a child or adolescent have the capability to fully comprehend and appropriately weigh the short- and long-term risks and benefits of medical treatment and procedures? At what point should the inherent right of adults to consent to and refuse medical treatment be extended to children? What level of information about a medical condition and its treatment should be routinely shared with a child or adolescent?

The legal age for independent decision making has customarily been set at 18, but some younger individuals have greater capacities for decision making than some adults. Furthermore, state legislative policies have extended legal decision making to adolescents younger than 18 (referred to as mature or emancipated minors) when they are serving on active duty in the military, self sufficient, married, or when it is thought that obtaining parental consent would hinder or delay necessary treatment

for specified disorders, most frequently substance abuse, contraception, and sexually transmitted diseases. State policies have also been highly variable in definitions of mature minors, enumerations of medical conditions to which minors can consent, and responses to parental requests for treatment information.

Parents' right to make decisions for their minor children is well established in common law and the U.S. Constitution. And through a doctrine of *parens patriae*, the state also has a clearly identified obligation to protect children and adolescents independent of parental approval. In medical decision making, *parens patriae* has mainly been applied only: (1) when seeking required parental approval would hamper a minor from receiving necessary medical treatment, e.g., treatment of a sexually transmitted disease; (2) when parental refusal of treatment would jeopardize the life of the child, e.g., refusal to treat juvenile diabetes; and (3) in attempts to define the rights and societal obligations afforded to children with terminal illness.

The right of refusal exercised by Andrew's parents requires respect. While one may not agree with their decision, they are exercising their fundamental right to refuse an intervention that lacks sufficient established benefit for Andrew for the state to step in and contravene their decision. Their request, however, does not fully abrogate Dr. Kessler's responsibilities in seeking to ensure what is best for her patient. A statement issued by the AAP Committee on Bioethics in 1995, noted that "the pediatrician's responsibilities to his or her patient exist independent of parental desires or proxy consent" [2]. The ethical dilemma as to whether Andrew should be afforded the opportunity to be presented with important medical information remains unresolved, at least temporarily.

One may also wonder whether Dr. Kessler "did the right thing" by electing to have an initial conversation with Andrew's parents, excluding him from the process. Parent-physician discussions that exclude the child and early adolescent are frequently held for delivering the initial diagnosis in serious and life-threatening conditions because doing so allows parents to express their fears and concerns freely, which they might not do in the presence of their child. Such conversations are usually followed by discussions with the child or adolescent and include both information and assent for treatment. Excluding the patient, however, provides at least tacit deferral to the parents as ultimate decision makers, perhaps contributing to the ethical dilemma.

What course of action would I have pursued if I were the oncologist encountering Andrew and his family for the second time? Given the context of Andrew's age, life-threatening illness urgently requiring therapy, and respect for parental rights, I concur with Dr. Kessler's decision to accept, at least initially, the parents' refusal to discuss the therapeutic option, one that is not universally employed and has only incremental benefit. I would remain concerned, however, about continuing on a course where medical options were not discussed with Andrew. The nature of Andrew's illness will most likely require me to have at least daily contact with him and his family during the next several weeks. During this time, I would emphasize to

the parents the importance of sharing information with Andrew about his treatment and obtaining appropriate assent. As my relationship with Andrew and his family strengthens, I would seek to provide the parents with additional information about sperm banking to further educate them and resolve their misconceptions. If treatment is successful, Andrew will be in remission and medically more stable in approximately 1 month. Perhaps by this time the parents will be less stressed and more informed about sperm banking and will recognize the importance of sharing medical information with Andrew enough to permit a discussion with him on this subject.

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Commentary 2

by James L. Klosky, PhD

The American Society of Clinical Oncology asserts that oncologists have a responsibility to discuss infertility risk with all patients treated during their reproductive years and that these discussions should take place as early as possible [1]. At the same time, physicians are charged to “do no harm.” If Andrew’s parents believe that their son will get upset at the suggestion of fertility preservation outside of the context of marriage, the physician’s duty to discuss risk must be balanced with the potential of causing psychological harm to both patient and family. Dr. Kessler, the oncologist in this case, is further challenged due to her unfamiliarity with this family (second appointment) and her surprise regarding the parents’ insistence that sperm banking not be addressed with their son. There are many factors that influence an adolescent’s candidacy for sperm banking including cancer diagnosis, treatment acuity, age, Tanner stage, religious orientation, cognitive functioning, and emotional maturity. I provide recommendations specific to this case study, but they may be generalized to other adolescent patients.

Communicating Fertility Risk in the Pediatric Oncology Setting

We know that both Andrew and his parents were present during the review of potential infertility as a result of his treatment for AML. Later, Dr. Kessler chose to

initiate the discussion of sperm banking when Andrew was outside of the clinic room, and, because of his parents' insistence, she agreed to refrain from further sperm-banking discussions. In retrospect, Dr. Kessler should have made a brief statement on sperm banking at the time of fertility-risk disclosure in the presence of both Andrew and his parents. Ideally her statement would have included the information that sperm banking is often recommended prior to the initiation of AML treatment to preserve the patient's ability to father children in the future, as she was describing the various body systems affected by AML treatment. The advantage of this brief introduction is that it exposes the patient and his parents to the idea of fertility preservation without demanding an immediate response from them. Upon completion of the late-effects review, Dr. Kessler could have inquired globally whether the family had questions about "anything that I reviewed today," thus creating another opportunity for sperm-banking discussions in a low-demand context. This approach would have also increased the likelihood of private discussion between Andrew and his parents, which in turn could have facilitated more expedient sperm-banking decision making and improved decision satisfaction regardless of the outcome.

It is not uncommon for teenagers and their parents to be highly distressed at the time of cancer diagnosis and during informed-consent and assent processes. In particular, difficulty in remembering and processing information related to cancer survivorship is often reported when the acute focus of the family is on cancer cure. To redress this problem, oncologists and their medical teams frequently assess and reassess the family's understanding of cancer treatment and provide a stream of supplemental information on treatment-related topics designed to facilitate prompt and informed decision making and psychological adaptation to diagnosis.

Correcting Misconceptions, Promoting Flexible Thought, and Making Effective Referrals

Prior to a diagnosis of pediatric cancer, most families have never considered banking sperm. Furthermore, when teenagers think about reproduction, most focus on avoiding pregnancy—not preserving fertility. Consequently, many families are unacquainted with the process, demands, or options related to sperm banking and may be quick to make judgments or develop misconceptions regarding this sensitive topic. It's in these cases that oncologists (or other members of the medical team) can significantly influence the decision-making process by sensitively querying familial rationales for not banking sperm, while at the same time correcting any misconceptions that the family (or parents in this case) may have.

The case study indicates familial communication about sexual behavior in Andrew's family is poor and lacks recognition (or knowledge) of normal psychosexual development. Andrew's parents have made two errors that can be modified. First, there is an assumption that by banking sperm, reproduction will take place outside of the confines of marriage. A clinician could reframe this assumption and explain that by banking sperm, Andrew and his future wife will maintain the option of having biological children (and grandchildren) in the future. Although it was not explicitly

stated, it appears that both of Andrew's parents object to the traditional method of collecting sperm (i.e., masturbation). Information on epididymal sperm aspiration, testicular sperm aspiration, or electroejaculation (all of which can take place under sedation) could have been highlighted as "nonsexual" options that could be exercised with their consent and Andrew's assent.

Information of this sort could have also influenced Andrew's father, who views his son as a "good boy who would never think about doing anything like that." Rather than resigning to this rigid style of thinking (good boy versus bad boy), the physician could encourage Andrew's father to think more flexibly and consider sperm banking as a function of fatherhood and human development. Instead of focusing on the psychosexual, physical development could be emphasized with brief education addressing Tanner stage and secondary male characteristics (increased muscle mass, body hair, and deepening voice) as markers of impending manhood. If Andrew's father seems receptive to this line of counseling, Dr. Kessler could go further and introduce or normalize the involuntary experience for nocturnal emission as the body's way of demonstrating its biological readiness for fatherhood. Questioning resistant parents about their own identity as parents and interests in grandparenting can also facilitate a productive discussion about sperm banking as a means of salvaging their child's fertility after cancer treatment.

Even senior oncologists with well-developed clinical acumen encounter families who identify barriers to sperm banking, including familial religious orientation, culture, tradition, socioeconomic status, perceptions of fertility risk, communication style, psychological functioning, and, as in this case study, refusal to discuss the pros and cons of sperm banking with the patient. When families present these or other barriers that fall outside of the medical scope, they should be referred to others within the hospital system who are trained in addressing the identified sperm-banking barrier(s). For example, families who are motivated to bank sperm but are conflicted due to their religious beliefs (masturbation, use of assistive reproductive technologies, etc.), should be referred to a hospital chaplain. Families experiencing banking-related conflict or anxiety should be referred to a clinical psychologist. Referral to social work is indicated if concerns develop regarding sperm banking, storage costs, or transportation to the fertility clinic.

A referral to a psychologist could have been helpful in reducing Andrew's parents' anxiety, which in turn affects flexible thinking. Furthermore, the consulted psychologist could facilitate increased communication among family members on topics such as infertility concern, sperm banking, discomfort with decision process, or the promotion of decision-making satisfaction regardless of the sperm-banking outcome. By utilizing a "barrier interventionist," Dr. Kessler may have maximized the likelihood of Andrew banking sperm.

Conclusion

Sixty-seven percent of male cancer survivors desire children and prefer biological offspring whenever possible [2-4]. Survivors who experience infertility are at

increased risk for emotional distress, including sadness and anger, particularly when fertility information was withheld at diagnosis [2, 5-9]. Infertility-related distress is a long-term issue that impairs intimate relationships and other quality-of-life outcomes up to 10 years post-cancer treatment among young adults [10]. One way to avoid these and other undesirable outcomes of infertility is to bank sperm. Currently, sperm banking among adolescent males is underutilized, although the reasons for this are not well understood.

This case represents a realistic situation that many of us encounter and struggle to resolve. It is our duty to communicate risk of infertility in a timely fashion and to recommend sperm banking when indicated. But in order to promote sperm banking among uninformed families, we must also correct misconceptions, promote flexible thinking, make effective referrals, and follow up with adolescents and families within the ethical confines of pediatric care [11]. Although it is often thought that sperm banking must take place prior to the initiation of cancer therapy, animal modeling suggests that developed sperm are stored in the epididymis up to 14 days prior to ejaculation, suggesting that sperm samples provided within 2 weeks of treatment initiation can be used [12, 13]. For those who initially refuse sperm banking, efforts to promote banking should continue during the first few weeks of treatment before the patient becomes azoospermic.

Sperm banking is not appropriate for everyone, and the needs of individual patients must be considered. Whether the goal is to improve decisional satisfaction, emphasize the possibility of fertility maintenance, or develop more flexible ideas of parenting, the goal of improving quality-of-life outcomes across all cancer survivors remains.

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ON CALL

Patient Autonomy and Physician Responsibility

Commentary by Patrick C. Beeman and Ryan C. VanWoerkom

Mr. Smith, 50, was HIV positive. Having given informed consent, he underwent cardiac catheterization following a positive stress test. He was found to have mild-to-moderate single vessel coronary artery disease. Mr. Smith did well during and immediately after the procedure and was discharged.

After discharge, however, he had complications and severe pain. He returned to the hospital the day after the catheterization and was found to have massive groin and scrotal swelling, diagnosed as scrotal hematoma. A vascular surgeon was consulted and reported that there was no need for surgical evacuation. Accordingly, Mr. Smith's hematoma was managed conservatively by elevation of the scrotum, and he was given analgesia for his pain. On admission, his hemoglobin was 12.3g/dl and remained stable throughout his hospital stay. Mr. Smith also received occupational and physical therapy. His hematoma decreased in size only minimally over the course of his stay, and he continued to complain of pain.

By hospital day 5, the primary team decided that Mr. Smith was medically stable and could be discharged safely to the extended care facility (ECF). There, physical therapy and the conservative management of his hematoma would continue. Upon mention of the plan for his transfer, Mr. Smith became upset. He remarked that the complication was not his fault and that, since the hospital "did this to [him]," the least it could do was provide him a place to recuperate. "I will leave when I'm ready," he stated.

The attending cardiologist had apologized to Mr. Smith for the complication when he was readmitted to the hospital. Now the cardiologist politely explained that, given his HIV status, an extended hospital stay was dangerous for him because of "the bad bugs that live here." This made matters worse. One of the medical students on the team later discovered that the patient had misinterpreted the cardiologist's statement to mean that his HIV status increased the risk of infection for others. All in all, Mr. Smith felt that he had not been treated well, stating he did not appreciate what he perceived to be the flippant way in which the attending cardiologist had announced his HIV status for others in the room, including the patient's roommate, to hear. Further, he said, one morning when he had not felt well enough for physical therapy and asked the therapist to return in the afternoon, a nurse had said to him, "You can lie around at an ECF just as easily as you can lie around here." Understandably, this offended Mr. Smith. He was discharged from the hospital after 14 days.

Commentary 1

by Patrick C. Beeman

This case raises many ethical and professionalism issues: the importance of good communication in the patient-doctor relationship, the conflict between a patient's wishes and a doctor's clinical judgment, how one should manage the complications that inevitably occur, and others. But the chief ethical concern in this case is the classic conflict between autonomy and beneficence. What do we do when a patient's demands don't accord with the physician's judgment about what is in the patient's best interest—in this case, a short hospital stay?

Autonomy, the principle of patient self-determination, gained ascendance as a kind of uber-principle in medical ethics in the decades after 1970. Edmund Pellegrino, MD, chair of the President's Council on Bioethics and elder statesman of the discipline, has observed that, in our time, "the center of gravity of clinical decision making has shifted almost completely from the doctor to the patient" as a way to combat the "historical dominance of benign authoritarianism or paternalism in the traditional ethics of medicine" [1].

Pellegrino argues that the proper focus of autonomy, the reason it is owed respect, is the principle of beneficence. Paternalism is not synonymous with physician beneficence, nor is it compatible with either autonomy or beneficence. Beneficence means acting in the patient's quadripartite good, his or her biomedical, subjective, personal, and ultimate good [2, 3].

In this case, achieving the patient's *biomedical* good requires managing his hematoma and the complications related to it. By hospital day 5, it was apparent that this goal was well on its way to being met. The *personal* good of the patient, "what is good for humans as humans and members of the human community," includes maximizing his ability to decide for himself, to set his own course in life [3]. The achievement of this subtle and demanding aspect of the good lies in respecting a patient's autonomy, for instance, not coercing him into treatment with which he is uncomfortable, but enhancing his understanding so that agreement to decisions about his care spring from who he is as a rational, decision-making being. The *ultimate* good of the person—at once the most important and intrinsic of the four aspects of the good—involves respecting the religious, spiritual, and other all-important beliefs of patients. This case does not illustrate pursuit of that good, though certainly it was not openly or intentionally opposed. But it was principally the *subjective* good of the patient, the desires and wishes Mr. Smith identified for himself in relation to treatment, which posed the conflict in this case. Whatever the reason, Mr. Smith's subjective good included staying in the hospital on his own terms, not on those of his physician.

The miscommunications and recriminations that occurred at the outset of discharge planning complicated the case. What could have been done better? Knowing of the patient's dissatisfaction with his care (the attending had been forewarned by one of

the students about the patient's allusions to having a "legal case"), the physician might have taken into account the precariousness of the situation before bringing up the idea of discharge to the patient.

Admittedly, Mr. Smith was what some would call "a difficult patient," but the attending cardiologist, to be fair, had apologized to Mr. Smith. Still, a further exploration of Mr. Smith's understanding of his situation and his goals and frustrations was warranted. After discerning these, the search for common ground may have begun by providing the patient with realistic discharge options and explaining to him the physician's concerns regarding increased risk of nosocomial infections in HIV-positive patients [4-7]. The doctor's actions unquestionably were motivated by solicitude for Mr. Smith's biomedical good. At the same time, Mr. Smith's frustrations were exacerbated by a perceived high-handed disregard for his subjective good.

The focus on autonomy that we have experienced in medical ethics has encouraged greater participation by patients in their own care. Of course, doctors are not obligated to do whatever patients ask of them, but providing options such as, "Would you like to leave tomorrow morning or Wednesday?" rather than marching into the room during rounds and announcing that the patient must leave would have allowed the patient a measure of self-determination in his care. Such an action may have prevented the conflict between the patient's subjective interest in a lengthened stay and the biomedical good of preventing nosocomial illness while simultaneously maximizing the patient's autonomy in the context of beneficence.

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Commentary 2

by Ryan C. VanWoerkom for the MSS Committee on Bioethics and Humanities

The first commentator provides an illustrative account of ethical questions critical to a sound fiduciary physician-patient relationship. What is not adequately stated is that a thorough discussion of the risks and benefits of the cardiac catheterization as part of the informed consent process might have prevented some of Mr. Smith's anger or at least prepared him for the possibility of complications such as those he experienced.

In our relatively limited clinical experience, students pass through the majority of clinical inpatient rotations. Within this environment, time, priority management, urgency, and economics drive only the briefest of patient interactions. In less-pressing circumstances, offering better information organizes the patient's expectations for a workable treatment plan. This information would include a discussion of the patient's potential increased risk of adverse outcomes and modified subsequent recovery in context of his HIV status. If the patient chose the procedure after understanding the properly explained risks, he then would have stepped into the realm of autonomous decision making with a feeling of ownership of the adverse outcome. Moreover, a simple question, "I sense you are concerned about leaving the hospital; can you tell me about this?" would show empathy and might succeed in alleviating Mr. Smith's underlying apprehension.

Mr. Smith's HIV status should not only influence the management of his expectations but should serve as the source for another vital aspect and discussion point in this case and in ethics— patient confidentiality. Understandably, it is difficult in crowded hospitals to maintain the highest standards of confidentiality. Asking the nurse to take Mr. Smith's roommate for a walk, however, or asking the patient if he felt up to joining you on the couch or bench in a corner of an isolated hall, or simply making an effort to speak more softly to conserve his confidentiality might have instilled confidence that you value preserving his privacy—perhaps more so in the offering than in the actual event. The Council of Judicial and Ethical Affairs at the American Medical Association states, "Such respect for patient privacy is a fundamental expression of patient autonomy and is a prerequisite to building the trust that is at the core of the patient-physician relationship.... Physicians should be aware of and respect the special concerns of their patients regarding privacy" [1].

The nurse's comment illustrates an important aspect of expectation management that is often overlooked. If the expectations of the entire team are not unified, discord can ensue. Rather than helping resolve Mr. Smith's concerns, the nurse fed into his

perception that the staff wished to be free from him by passing on his care to an ECF. Perhaps this perception engendered a fear of abandonment, or it might have suggested to Mr. Smith that being discharged to the ECF was a punishment. In either case, the comment fueled Mr. Smith's sense that his autonomy was not being respected and that the physicians' purported beneficence was really paternalism. The pendulum of autonomy may swing toward the patient in many contemporary circumstances. A physician who fully understands, accepts, and exercises the professional rights of his position will teach the patient about the risks and benefits of procedures as related to their own health. He or she will explain the finite nature of medical resources with their accompanying financial obligations as well as alternatives, in a cooperative and confidential environment in conjunction with health-care staff. If these guidelines, and those suggested by the first case commentator, are heeded, greater understanding may pervade the healing halls of hospitals and clinics.

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Note from the MSS Committee on Bioethics and Humanities: This is not a comprehensive evaluation of the case discussed here, but rather a catalyst for further discussion and an evaluation of a few key points that were deemed to be important talking points in this particular case.

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The facts of this case have been changed so that it does not describe the actual experience of the student-author or of a specific patient. Resemblance of the resulting case to the actual experience of a specific student or patient is coincidental.

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MEDICAL EDUCATION

Tethered to the Diving Bell: Beyond Vulnerability to Autonomy

Denise M. Dudzinski, PhD, MTS

Respecting the autonomy of patients is complex and subtle. First and foremost, patients with serious and disabling illnesses experience *dependence* because their ability to express themselves is compromised in some way. They are vulnerable and need help. *The Diving Bell and the Butterfly* by Jean-Dominique Bauby tells the dramatic true story of a man living with locked-in-syndrome (LIS). His motionless body belies his desire to interact with others. As Bauby's memoir richly describes, autonomy is not simply a matter of having a will of one's own; it depends on our ability to communicate with others and on others' willingness to listen and connect with us. Because it was virtually impossible to tell what Bauby was feeling or thinking, caregivers had to find a way into his diving bell. They did this first by diagnosing and treating him, and second by finding ways to help Bauby express himself. By paying attention to his vulnerability, they helped restore his autonomy. When internal medicine residents and I discuss the memoir, we notice the intricacies, surprises, and challenges of respecting patient autonomy. The residents also empathize with the isolation experienced by seriously ill patients, which can lead to more compassionate care.

In *The Diving Bell and the Butterfly*, Bauby describes his experience of being locked in. The English translators chose "diving bell" over "diving suit" for *Le Scaphandre et le Papillon*, an apt metaphor for his experience of feeling like a prisoner. Used as a base for divers, a diving bell is an airtight underwater chamber suspended by a cable. The fate of the divers rests in the hands of the surface crew who ensure pressurized and breathable air is pumped into the bell. Bauby is, at times, autonomous. He is also profoundly vulnerable. For physicians who respect him, autonomy and vulnerability are bundled together. Medical caregivers control the breathable air entering the "diving bell," and Bauby is tethered to them, not only for his life but for his identity.

After recovering from the trauma of a pontine stroke, Bauby could rightly be described as autonomous. Though sounds were distorted, he could hear, had the use of one eye, and could swivel his head, but was otherwise expressionless and inert. He had decision-making capacity and through painstaking effort could make his wishes known. Bauby could be entrusted to know what was best for him. Still, he needed others to help him convey his wishes and values. A major goal of his treatment for LIS was to help him regain his autonomy and to give him new tools for asserting himself. His memoir is a testimony to the irony of autonomy: the way to respect autonomy is often to pay vulnerability its due.

Autonomy can be interpreted in psychological as well as ethical terms. People need the psychological and cognitive ability to choose their life plans freely and act on them independently [1]. Due to our inescapable reliance on others, no one is fully autonomous, but each person self-legislates in varying degrees and scope. Those with a sufficient degree of autonomy—individuals who are largely in charge of their lives and decisions—are called substantially autonomous persons [1]. Even those without fully realized autonomy retain capacity to make some meaningful choices. The preferences of children and cognitively impaired patients matter, even when a surrogate is needed. Ethically, we respect autonomy when we allow health care decisions to be guided by the patient’s particular values, worldviews, and life plans. Respect for autonomy is a corrective to paternalism, which presumes doctors have the authority to decide what is best even for substantially autonomous patients.

Through diagnosis and treatment, doctors shape Bauby’s identity and support his autonomy. His friends report the exchange of gossipers at a Paris cafe. “Did you know that Bauby is now a total vegetable?” “The tone of voice,” Bauby observes, “left no doubt that henceforth I belonged on the vegetable stall and not to the human race....Instead I would have to rely on myself if I wanted to prove that my IQ was still higher than a turnip’s” [2]. Bauby was “in there,” but to find him, caregivers had to reach in through the placid facade to the man inside. Waiting for some assertion of autonomy would have been disrespectful of him. So what did they do? They encroached upon his isolation and interpreted his silent cries.

The lifeline into Bauby’s diving bell was the communication system invented by his speech therapist. Visitors read letters of the alphabet to him in the order of the frequency of their occurrence in the French language, and Bauby blinked when the letter he wanted was read aloud. Hours were devoted to crafting and memorizing the chapters of his memoir, which was dictated letter-by-letter. The system was used by most of his friends but only two hospital employees.

So I usually have the skimpiest arsenal of facial expressions, winks, and nods to ask people to shut the door, loosen a faucet, lower the volume on the TV, or fluff up a pillow. I do not succeed every time. As the weeks go by, this forced solitude has allowed me to acquire a certain stoicism and to realize that the hospital staff are of two kinds: the majority, who would not dream of leaving the room without first attempting to decipher my SOS messages; and the less conscientious minority, who make their getaway pretending not to notice my distress signals [3].

His description makes us wonder why so few members of the care team learned his communication system. Perhaps questions were posed by physicians, and the speech therapist, with the luxury of time, helped Bauby answer. Perhaps some found ways to discuss many subjects via Bauby’s SOS signals, but any physician who tried to learn the system and patiently waited for a specific response demonstrated unquestionable respect for Bauby’s autonomy. One of the great dilemmas of his new existence was the forced absence of repartee. As awkward and laborious as

communicating with him must have been, it is excruciating to imagine Bauby's perspective—having a quick response on the tip of his tongue without the ability to command speech. *The Diving Bell and the Butterfly* reminds us that what we owe patients is not respect for autonomy *per se*, but respect for persons, which always involves delicately balancing autonomy and vulnerability.

While describing the slow awakening to his new life of grave disability, Bauby rarely rages against medical staff or indulges in self-pity. When I discuss this memoir with internal medicine residents, we always talk about the following passage.

I have known gentler awakenings. When I came to that late-January morning, the hospital ophthalmologist was leaning over me and sewing my right eyelid shut with a needle and thread, just as if he were darning a sock....What if this man got carried away and sewed up my left eye as well...the one tiny opening of my diving bell [4]?

Despite frantic blinking to summon the doctor's attention, Bauby concludes, "Disinclined to chat with normal patients, he turned thoroughly evasive in dealing with ghosts of my ilk, apparently incapable of finding words to offer the slightest explanation" [5]. If caregivers are the lifeline to Bauby's diving bell, then this doctor was certainly suffocating him.

The residents and I wonder aloud about the ophthalmologist's perspective. How might he have described the experience? We recognize that sometimes physicians must focus primarily on the task at hand, not the patient's experience of it. Residents also recognize the apathy and numbness that is a precursor to burn-out. When a physician desperately needs rescue himself, it can be difficult to muster sympathy even for the most vulnerable of patients. Perhaps this physician and Bauby *shared* the experience of isolation [6]. While the physician's suffering and isolation is vastly different than Bauby's, the memoir allows us to discuss how residency can feel like being trapped in a diving bell. Overworked residents sometimes feel like they have been stripped of their identity, executing the judgments of attending physicians with whom they may or may not agree. Here, too, the solution is to recognize and pay respect to one's vulnerability—to reach out for help and to let colleagues reach in and pull you out of isolation.

Respect for autonomy is important, because competent patients only feel respected if their individual desires and preferences are taken into account. Bauby had to reinvent himself and mourn the loss of his pre-stroke self [7]. The memoir moves between vivid descriptions of the man he used to be, his imagination (both butterflies), and the diving bell of LIS. Respecting his autonomy meant riding waves of indecision, contradictory preferences, and loss of identity as he settled into a life no one would choose. "I have begun a new life, and that life is here in the bed, that wheelchair, and these corridors. Nowhere else" [8]. It meant searching for the animated mind trapped in a motionless body. Those who attended to his vulnerability *first* guided him as he

groped toward the substantially autonomous person he knew himself to be or had to create because his illness had changed him. Sometimes this breath of fresh air is as important as the medical treatment, because it gives patients the will to keep searching for and reinventing themselves.

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MEDICAL EDUCATION

Teaching Physician Decision Making in a Technical Age

David Segal, PhD, and Richard L. Fernandez, MD

Traditional medical school ethics curriculum introduces students to the concepts of patient autonomy, informed consent, and medical uncertainty, which are central to contemporary biomedical ethics and the doctor-patient relationship. New guidelines and training programs have been developed in medical education to improve patient-doctor communication and support patients' active role in the shared decision-making process, but there is limited evidence to support the effectiveness of these efforts in practice. While the students understand the theory of medical uncertainty in the basic science years, this theoretical understanding is often replaced in the clinical training years by a reluctance to reveal uncertainty that, they fear, may convey a lack of medical knowledge and confidence.

The standard medical ethics curriculum assumes that patients and physicians are autonomous actors within the limited confines of their individual bodies or biologic space. This biomedical domain, however, must now be expanded into a somato-psychosociocultural model to include electronic spaces such as virtual environments, social networks, collaborative networks, and intelligent agents. The decentralized, social collective worlds offered by new social networking technologies over a borderless Internet empower each user with shared and cooperative interactions that can heighten their individual autonomy. This new technological architecture defines an "electronic" space that must be considered along with the biological space interactions that impact an individual's ability to make their own decisions.

Collective sites such as PatientsLikeMe have shown that thousands of people are willing to share their medical records, healthcare experiences, and outcomes for the benefit of other patients, caregivers, physicians, researchers, and anyone else who can help make patients' lives better. This global collaboration provides patients with real-world data and real-life information that can impact their own health care decisions. The power of these new tools can reshape our minds. Did we really believe we could collaboratively build and inhabit virtual worlds all day, every day, and not have it affect our perspective?

The 21st-century medical school should integrate adaptive, simulation-based training into its curriculum to offer individual and team learners with the optimal mix of synchronous experiences and instruction to rapidly develop robust and effective decision-making skills and other complex cognitive processes to deal with uncertainty. These technological advances allow for continuous performance

measurement and assessment along with empirically validated instructional interventions.

Computer-based decision support tools are not meant to replace live medical instructors or health professionals but to display the complexities of each individual patient case and decision-making process. Medical education must provide experiential learning to help students gain skill in assisting patients to make decisions about their own health care. It is imperative that we minimize our students' fear of failure so they aren't afraid of thinking outside the box, even though that means possibly making mistakes. Allowing students to confront these experiences in a "low-stakes," virtual space gives them insight into the different modes of patient and physician decision making and builds their confidence in managing actual clinical encounters.

One such innovative online, case-based, adaptive-training solution is called MyCaseSpace. This virtual clinic has state-of-the-art simulation and intelligent agents. It invites students to interact with open-ended, problem-solving case scenarios that have basic science and clinical outcomes. The optimal way to illustrate the consequences of decisions is to simulate the multiple outcomes for each decision made by doctor, patient, family, and other health care actors in the scenario. This adaptive training system integrates multiple sources of patient data to provide real-time, sophisticated, expert performance evaluation of the learner's knowledge, skills, and abilities. The system can also support the decision-making process by providing real-time risk- and cost-benefit information for each alternative outcome. The advanced display capabilities and intelligent agents provide real-time feedback, scenario modification, automated cueing, and synchronous collaborative decision-making strategies. Both the manner and context in which information is presented can alter the autonomous boundaries that influence the decision-making process. This solution has been successfully used to significantly improve both individual and team-based student and faculty development using interactive patient cases [1].

The following case conveys typical challenges of the patient-doctor relationship and respecting patient autonomy.

Mr. W. was admitted to an intensive care unit with chronic and progressive symptoms diagnosed as the result of a tumor. He had a small but real chance of leaving the hospital alive if he submitted to invasive treatment. But Mr. W. felt that he had suffered enough and requested supportive care only. Before making a final decision, though, Mr. W. asked to speak with his primary care physician, Dr. K. Dr. K. ignored Mr. W.'s decision for supportive care, strongly emphasizing the patient's small chance of recovery and his own personal belief that giving up was not acceptable. Dr. K. finally convinced Mr. W. to undergo the surgical procedure. Mr. W.'s surgeon, Dr. M, made sure that Mr. W. understood his options and the probabilities associated with them and then complied with Mr. W's request for supportive care of chemotherapy and pain management, without sharing his own opinion, which was that the patient was making a serious mistake. Dr. H., Mr. W's

internist, spent a considerable amount of time with Mr. W., exploring various alternative treatments and offering additional information about the likelihood of success, while recommending that the patient try a more aggressive therapy. After some in-depth conversation, Dr. H. realized that Mr. W. appeared to be well informed and confident in his decision, so he initiated a palliative care plan for the patient. Dr. L., the oncologist, explained Mr. W.'s condition and spent a considerable amount of time listening to Mr. W.'s personal views about his lifestyle, family, religious beliefs, and future goals. Dr. L. explained the condition and the prognosis for several different treatments and the expected goals for each therapy to Mr. W. After a pause, Dr. L. recommended the surgery and explained the benefits of this approach in terms of Mr. W.'s expressed life goals and in comparison with the other possible treatments. Mr. W. asked Dr. L. to elaborate on the technical aspects and adverse effects for each treatment option which Dr. L. gladly did. Mr. W. felt relieved that Dr. L. had taken the time to explain the condition and treatment choices so that he could fully understand what would happen and how it would affect his quality of life afterwards. Mr. W. was amazed that Dr. L. was interested in hearing his thoughts about his condition and that Dr. L. was willing to spend whatever time was needed to answer all of his questions. In the end, Mr. W. made the decision to undergo the surgical procedure with no reservations.

Delivering this case in an open-ended digital format allows the conversations between the patient and each doctor to change with each interaction, while being linked in real-time to the patient's physiological and mental indicators. The patient's ability to make an informed decision can be evaluated based on the change in patient physiological, mental, and communication indicators. This type of simulation can dramatically illustrate the manner in which the physician might engage in open dialogue and inform the patient about his or her condition and therapeutic possibilities and discuss how the patients' values and personal beliefs can impact the decision making process. The patient's condition can also change depending on the decisions he or she makes.

The challenge for our 21st century medical education curricula is to employ new tools that simulate experiential learning and combine clinical evidence and expert guidance with patient-based scenarios that demonstrate the complexity of shared patient-physician decision making.

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JOURNAL DISCUSSION

The Belmont Report's Misleading Conception of Autonomy

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National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Bethesda, MD: US Government Printing Office; 1978.

Practically all human subjects research in the United States is regulated by the Federal Policy for Protection of Human Research Subjects [1]. That policy was formed by the Department of Health and Human Services in the late 1970s and early 1980s, and was later adopted by 14 federal departments and agencies. The policy's ideological foundation had been laid by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [2]. The commission's 1978 report, generally known as the Belmont Report, identified three ethical principles as basic to the ethical guidance of research involving human subjects: respect for persons, beneficence, and justice. This influential analysis has provided the background for ethics policy concerning human subjects research to this day.

Despite its political success, the Belmont Report is not beyond philosophical criticism. In what follows, I will argue that the report makes a philosophical error in its attempt to derive moral requirements for informed consent from the principle of respect for persons. Although neither the principle of respect for persons nor the need for robust informed consent policy will be questioned, I will argue that the report's manner of linking these two is based on a misguided conception of autonomy. Instead of invoking the autonomy of the consentor, the report should have based the duty to seek informed consent on the status of the researcher as an autonomous moral agent.

The Belmont Report and Respect for Persons

Since the publication of the Belmont Report, the standard ethical justification for informed-consent policy has been that obtaining informed consent is a way of respecting persons, which in turn is a fundamental moral requirement. The report states:

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied [3].

Informed consent provides more than an opportunity for choice; it provides choice based on adequate information. But why would it be disrespectful to offer choice without information, and how are we to judge when the provision of information is adequate? The report's answer is that persons with the capacity for self-determination—those capable of deliberation about personal goals and of acting under the direction of such deliberation—must be treated as autonomous agents; *their autonomy must be respected* (emphasis added). The report explains that:

To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so [3].

Persons with a capacity for self-determination should thus be (1) free to act on their considered judgments as long as they don't harm others, and (2) informed as needed so that they can form a considered judgment concerning how to act. Together, these statements imply that respect for autonomy requires informed consent.

Self-Determination and the Duty to Inform

Respect for persons is surely a fundamental moral principle. It is less clear what to make of the Belmont Report's attempt to derive from that principle a general duty to inform, i.e., a duty not to "withhold information necessary to make a considered judgment." It would be implausible to think that we are all generally obligated somehow to inform each other, out of mutual respect, in every way that might be helpful for the formation of considered judgments. There is simply no such general duty. Instead, a duty to inform out of respect is inherent in specific contexts of personal and communicative transactions [4]. For example, when money is borrowed, the lender and borrower must be mutually informed about terms and conditions. When service is rendered, the provider must similarly inform the client about the service and its cost. The same applies, only with greater moral force, when the service carries substantive risks for the client or is physically or psychologically invasive. It would be disrespectful to expect the client to agree to such services without being informed about their nature or probable risks and benefits.

Such behavior would not only be disrespectful but also potentially harmful and unfair to the client. It is therefore quite possible that informed consent receives part of its justification from considerations of beneficence and justice. This is not the spirit in which it is presented in the Belmont Report, however, which explicitly states that "the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons" [3].

It is beyond the scope of this article to examine the ways in which the principles of beneficence and justice underwrite requirements for informed consent. In the

absence of such examination, however, the report's emphasis on respect for persons as the main foundation for informed consent seems quite unreasonable in the context of human subjects research. Informed consent should not be the primary tool for preventing research subjects from harm and ensuring fairness; instead, ethics governance should ensure that subjects are not exposed to unreasonable risks or treated unjustly. To put the main burden of assessing the risks and benefits of participation on the individual subject through informed consent would indeed be unfair.

The primary role of informed consent seems better understood as a way of respecting each person as a rational agent who enters into agreements as a moral equal based on honest information. In its secondary role, informed consent protects the subject's well-being, because (1) judgments of what is burdensome or beneficial are often relative to the individual's conception of the good, and (2) the experience of being coerced, deceived, or manipulated is generally a strike against one's well-being.

In typical cases of human subjects research, it would clearly be disrespectful and maleficent to omit informed consent. Infamous failures in this regard were indeed a major motivation for the establishment of the National Commission and for the subsequent regulatory framework for research ethics that received its justification from the Belmont Report. The authors of the report, however, made a mistake in the way they chose to justify informed consent. They tried to argue that informed consent is morally required because it promotes self-determination, i.e., informed personal deliberation leading to the formation of a considered judgment. Such deliberation is obviously valuable, but the mere fact that something is valuable, even intrinsically valuable, does not entail a moral requirement to do whatever is necessary to promote it.

Each of us can promote only a limited number of valuable goals. There will always be an infinite number of goals that we might have promoted but didn't, and this does not mean we have failed morally. Similarly, a human subjects researcher might be sufficiently interested in promoting the self-determination of his research subjects to take measures to inform them about the research with its risks and benefits.

But suppose, hypothetically, that he is not? Merely to point out the value of self-determination, as the Belmont Report seems to do in its arguments for informed consent, may not be enough to persuade him. Why should he value these subjects' self-determination more than, say, the maximum cost-effectiveness of his research? Where's the argument that says he must, morally, weigh these values in one way rather than the other? And what if he can argue that omitting informed consent in this instance would ultimately lead to greater benefits to society or mankind? Simply to assert that self-determination is intrinsically valuable is insufficient because any measures to promote self-determination will come at a cost to some other intrinsic value that might then just as well be presented as a ground for an opposing moral duty. The value of self-determination can only be ranked in relation to that (or those) other value(s). (Interestingly, it is even possible to imagine, as Sarah Buss has, a

person who genuinely values self-determination and yet, without contradiction, sees nothing wrong in manipulation and coercion [5].) So valuing self-determination will not alone get us very far in the direction of justifying requirements for informed consent.

An Alternative Approach

Fortunately, there are alternatives on the philosophical menu. The term “autonomy” was first introduced to ethical theory by German philosopher Immanuel Kant [6]. Kant’s conception of autonomy differs greatly from the one indicated in the Belmont Report [7, 8]. The Belmont definition of autonomy (as self-determination) describes a psychological capacity for personal deliberation and action, a capacity that individuals may enjoy and exercise to various degrees. For Kant, by contrast, our autonomy is the free exercise of our practical reason in accordance with the good, and consists in the fact that the practical reason we all possess has direct implications for how we should act, no matter what our individual desires might be. More specifically, practical reason demands of all of us that *we never use humanity in our own person or that of another merely as a means but always at the same time as an end in itself* [6]. This principle, often referred to as Kant’s Formula of Humanity (FH), is indeed relevant to the morality of informed consent, because it implies a prohibition against coercing and deceiving human beings, as well as an obligation to benefit others and avoid harming them.

In addition to providing this promising lead toward a normative principle, the Kantian conception of autonomy puts us in a better position to address the hypothetical researcher who valued cost-effectiveness more than the self-determination of his research subjects. If we assume that the researcher has true autonomy, in Kant’s sense of the word, it follows that he has an obligation not to deceive or coerce his human research subjects.

Implications for Informed Consent

With the Formula of Humanity in hand, we are in a better position to consider when informed consent is required and what should count as “adequate standards of informed consent.” Kant scholars generally agree that the most plausible candidates for Kantian duties are the duties not to coerce or deceive rational agents [8]. According to Wood, for example, “coercion and deception obviously violate FH because they achieve their end precisely by frustrating or circumventing another person’s rational agency and thereby treat the rational nature of the person with obvious disrespect” [9]. Granting this, informed-consent procedures are justified by FH to the extent that they serve the purposes of noncoercion and nondeception.

The remaining question is which standards of informed consent are likely to serve these purposes. O’Neill claims that “informed consent is ethically important because it adds a tough safeguard by which individuals can protect themselves against coercion and deception” [8]. At the same time, she warns that the tendency to increase the amount and specificity of information and to insist on informed-consent procedures in every possible context is not warranted by this goal and can be

contrary to other morally important purposes, such as beneficence, public health, trust, and trustworthiness. Her suggestion is that, instead of inflating informed consent in a misguided attempt to solve all moral problems through one instrument, we should try to make sure that patients, research subjects, and tissue donors have control over the amount of information they receive and whether or not to go along with a proposed course of action (therapy or research). The danger of their being deceived or coerced is effectively limited when they “know that they have access to extendable information and that they have given rescindable consent” [10].

This suggestion seems plausibly motivated by Kant’s FH, and it implies that research ethics is not reformed by every additional demand placed on the informed-consent process. All such demands must serve the purpose of minimizing deception and coercion, and it is possible to imagine requirements for more information processing after that purpose has been served. On the Kantian view, the ultimate point of informed consent policy is not to increase endlessly the incidence of personal deliberation on the subject’s part, but rather to decrease the incidence of manipulation, deception, and coercion on the researcher’s part; the demands of autonomy bind the researcher. In fact, insisting that patients or potential subjects engage in extensive deliberation and information processing may arguably have the effect of frustrating their self-determination if they are neither willing nor able to engage in such efforts. Attempts to implement inflated informed-consent procedures may thus bespeak inadequate respect for persons who would rather not have the responsibility of deliberating and reflecting on the pros and cons of what they are being offered.

Conclusion

The Belmont Report rightly insists that informed-consent policy is justified by respect for persons and considerations of autonomy. The justification, however, should be along the lines of Kantian autonomy, basing informed consent on the Formula of Humanity and not on the value of self-determination. Informed consent may of course have unrelated benefits, such as helping individuals protect themselves from harm and exert control over their lives. These benefits will not, however, justify the significance informed consent has been given in bioethics in the past few decades. Insofar as that emphasis is justified, it rests on deeper considerations of real respect for persons.

This conclusion is of more than mere academic interest because the Formula of Humanity will guide our judgments about informed-consent policy differently than the Belmont Report does. Policy will no longer be based on how far it goes in the direction of offering people opportunities for personal deliberation. Instead, it will be rated by how well it protects people against deception and coercion. This difference in approach should certainly lead to policies that are different—perhaps less demanding and more flexible—than those that are naturally supported by the Belmont Report.

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CLINICAL PEARL

Prognosis and Therapy after Cardiac Arrest-Induced Coma

Megan Alcauskas, MD

Cases in which a family must make difficult, life-and-death decisions for a loved one are always complicated—both for the decision makers and for the medical team. Family members, often coming to the situation with inaccurate or unrealistic views about what modern medicine can achieve, struggle to understand unfamiliar and frightening medical concepts, all the while dealing with guilt, stress, and grief. Members of the health care team frequently find themselves navigating potentially volatile family dynamics while attempting to do their best for a patient who is caught in a medical gray area.

The role of a neurologist in these circumstances is to provide as much prognostic information as possible to help guide the decisions of both the family and the medical team. Timely, accurate information can be the key to avoiding misunderstandings and anxiety and to promoting a decision with which everyone is comfortable. A neurologist assesses the situation by examining the patient, initially and over time, for behaviors and reflexes that suggest or portend consciousness and other higher brain functions and uses that information to prognosticate the patient's medical course.

Consciousness and Coma

Consciousness is defined as an “awareness of self and environment,” although the boundaries of consciousness and how to definitively determine its presence are still debated in the neuroscientific, bioethical, and philosophical communities [1]. *Coma* is defined as “unrousable unresponsiveness,” or “the absence of any psychologically understandable response to external stimulus or inner need” [1, 2]. Given the ambiguity of these definitions and the difficulty in determining consciousness, many physicians avoid using these terms altogether and instead describe the patient's behavior.

Coma is not a permanent state, and comatose patients who do not die begin to awaken within several weeks, regardless of the severity of the underlying brain injury [1]. Some patients may open their eyes and demonstrate limited movement without ever regaining consciousness or attaining higher mental functioning. The term for this condition is *persistent vegetative state*, and these patients can survive for decades without ever improving neurologically [1].

Hypoxic-Ischemic Coma

The case of [Mr. Abdullah](#) presents a patient in a comatose state as the result of a cardiac arrest, one cause of hypoxic-ischemic coma, a condition with many etiologies, all of which lead to brain tissue damage from lack of oxygen. Cardiac arrest causes the cessation of cerebral blood flow, which produces loss of consciousness within 6 seconds [3]. If oxygen is restored immediately, consciousness can return in seconds to minutes. Two minutes of anoxia can cause focal damage. If the anoxia lasts longer than 4 minutes, brain cells begin to be lost permanently [4]. When ischemic anoxia lasts longer than 10 minutes most patients do not regain consciousness [5]. The pathophysiology of hypoxic-ischemic cell death is that, as neurons are deprived of oxygen, the proteins and electrolytes necessary to maintain the membrane potentials (i.e., electrical charge inside the cell membrane relative to that of the fluid just outside the membrane) are depleted, causing the cell to depolarize and the cell body to swell. The swelling results in irreversible damage to the cell's contents, initiating cell autolysis [1].

The Levy Criteria

Twenty-five years ago, physicians had little to draw on besides their own experience to help guide the families of comatose patients in making decisions [6]. In 1985, recognizing the need of families and critical care physicians for an accurate and useful prognostic tool for patients in hypoxic-ischemic coma, David E. Levy, MD, and his colleagues at New York Hospital-Cornell Medical Center took advantage of new statistical tools and a large, existing dataset to create guidelines now called the Levy Criteria. The criteria predict a patient's long-term neurological outcome within the first few days after cardiac arrest [7].

Levy and his team analyzed 210 comatose patients after hypoxic-ischemic events, performing neurologic exams within the first day and then at intervals up to 14 days after coma onset. The patients were then followed for 1 year to record their outcomes, which ranged from continuous coma until death (from brain- or nonbrain-related conditions) to recovery of prior levels of function. Using a novel statistical analysis and algorithm, the authors created a tree that predicted best functional state within the first year based on early examination findings. Their results are summarized in table 1. Of note, the investigators found that neither patient age nor sex nor etiology of the coma had a significant impact on the patient's likelihood of recovery [7].

Therapeutic Hypothermia

After the Levy Criteria were published, physicians could deliver more accurate prognostic information to families of patients with cerebral ischemia after cardiac arrest, but until recently there was little that could be done therapeutically for these patients besides treating underlying pathologies, maintaining respiration and circulation, and providing other supportive care. In 2002, however, two studies were published, showing that patients who were made mildly hypothermic (to a temperature between 32 degrees and 34 degrees Celsius) for 12 to 24 hours following resuscitation after arrest due to ventricular fibrillation had significantly

better long-term neurologic outcomes than patients who were kept normothermic [8, 9]. The precise mechanism by which cooling benefits patients is unknown, but it is thought to relate to decreased cerebral oxygen consumption, the inhibition of excitatory neurotransmitters, and a reduction in damaging free radicals and intracellular acidosis [9].

In 2005, hypothermia after cardiac arrest was added to the American Heart Association guidelines for post-resuscitation care, but adoption of this protocol has been largely limited to major academic centers and tertiary care hospitals [10]. Reasons for this delay include the complexity of the protocol, which requires expensive cooling equipment, specialized training for physicians, nurses, and support staff, and the formation of a multidisciplinary team composed of emergency physicians, cardiologists, neurologists, and intensivists. Therapeutic hypothermia can provide real benefit to some patients and represents the first proven therapy to prevent brain damage after cardiac arrest.

For Mr. Abdullah and his family, the neurologist can best contribute by doing several careful neurological examinations over time and using his own experience and the historical outcomes literature, including the Levy Criteria, to give the patient’s family the best information about his chance of meaningful recovery. Research in the field of post-anoxic interventions is ongoing and in the near future we hope to be able to offer these patients scientifically proven therapies, in addition to our best prognostic efforts.

Table 1 Guidelines to predicting long-term neurologic outcome in hypoxic-ischemic coma patients [7].

	Patients with Poorest Prognosis	Patients with Best Prognosis
Time after Cardiac Arrest	<ul style="list-style-type: none"> • Neurologic Exam Findings 	<ul style="list-style-type: none"> • Neurologic Exam Findings
Initial Examination	<ul style="list-style-type: none"> • No pupillary light reflex 	<ul style="list-style-type: none"> • Pupillary light reflexes present • Motor response: flexor or extensor • Spontaneous eye movements: roving, conjugate, or orienting
1 Day	<ul style="list-style-type: none"> • Motor response no better than flexor • Spontaneous eye movements neither orienting nor roving conjugate 	<ul style="list-style-type: none"> • Motor response: withdrawal or better • Eye opening improved at least two grades from initial exam
3 Days	<ul style="list-style-type: none"> • Motor response no better than flexor 	<ul style="list-style-type: none"> • Motor response: withdrawal or better • Spontaneous eye movements normal
1 Week	<ul style="list-style-type: none"> • Motor response not obeying commands • Initial spontaneous eye movements neither orienting nor roving conjugate • Eye opening not spontaneous 	<ul style="list-style-type: none"> • Motor response obeying commands
2 Weeks	<ul style="list-style-type: none"> • Oculocephalic response not normal • Motor response not obeying commands • Eye opening not spontaneous • Eye opening not improved at least two grades from initial exam 	<ul style="list-style-type: none"> • Oculocephalic response normal

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HEALTH LAW

Donors Retain No Rights to Donated Tissue

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Autonomy has been defined as “the quality or state of self-governing” [1]. In a health care context, respecting autonomy means allowing patients to make their own medical decisions. It also means allowing individuals to consent to participate in clinical research and to donate bodily tissues for research purposes. The boundaries of autonomy blur, however, once donated tissues leave the body, and the recipient researcher or university accepts the tissues.

The law has never established clear ownership rights in donated human tissues [2]. Historically, researchers and institutions have assumed that they retain the right to “collect, study, store, transfer, or dispose of tissue specimens and the associated patient data,” such as patented gene lines or means of genetic testing [2]. Though the *Code of Medical Ethics* of the American Medical Association prohibits the use of human tissue and its products for commercial purposes without the informed consent of the donor, physicians and researchers have assumed that they can use patient tissues and other bodily substances to develop cell lines, genetic sequences, and other biologic products that may be financially rewarding [3]. Patents have been granted or patent applications filed for an estimated 20 percent of human genes [4]. Several court cases have challenged researchers’ assumptions.

Moore v. Regents of the University of California

In the first case of its kind, the California Supreme Court held in *Moore v. Regents of the University of California* that individuals do not have an ownership interest in their cells after the cells are removed from their bodies. John Moore sought treatment from UCLA Medical Center (defendant) for hairy-cell leukemia. His attending physician, Dr. David Golde, recommended removal of Moore’s spleen for therapeutic purposes. Golde and UCLA researcher Shirley Quan planned to use Moore’s spleen tissue—which was “of great value in a number of commercial and scientific efforts”—for scientific study, a fact they never disclosed to Moore [5, 6].

Golde and Quan continued research on Moore for several years, causing him to incur inconvenience and expense associated with travel from Seattle to UCLA for visits that Golde misrepresented as medical appointments in the interest of Moore’s health, when, in fact, the purpose of the visit was to draw samples for more research [2, 5-7]. Golde ultimately succeeded in developing a cell line from Moore’s t-lymphocytes, and Golde, Quan, and the Regents of the University of California obtained a patent for the cell line then worth an estimated \$3 billion [5, 6]. Golde

also negotiated agreements for commercial development of the cell line and products to be derived from it.

Moore initiated a lawsuit against Golde, Quan, and the Regents, seeking to recover a share of the proceeds from the patented cell line. While the court recognized a physician's duty to disclose personal interests—research or economic—when seeking informed consent for a medical procedure, it ultimately found that the resulting patented cell line was the product of *invention*, not of the *donor* [5-7]. Even if the excised cells initially belonged to an individual, those cells were legally and factually distinct from the resulting research product [2, 5, 6]. Thus, the court held that individuals *do not* have an ownership interest in their cells after the cells are removed from their bodies [2, 5, 6].

The *Moore* decision remained the authority on a researcher's right to donated human tissue until 2003, when the issue arose once again.

Greenberg v. Miami Children's Hospital Research Institute, Inc.

In *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, the U.S. District Court for the Southern District of Florida held that individuals have no property rights in body tissue and genetic material donated for research. The Greenberg family sued a physician-researcher and hospital after the researcher developed and patented a prenatal genetic test using blood and tissue samples donated by their family and others. The donated genetic material was used in the study of Canavan disease, a rare and fatal genetic disease that occurs most frequently in Ashkenazi Jewish families [8].

Daniel Greenberg had approached Dr. Rueben Matalon, a research physician, to request his assistance in discovering the genes associated with Canavan so that tests could be administered to determine carrier status and allow for prenatal testing [6, 8]. Greenberg and other individual plaintiffs began supplying Matalon with genetic material including blood, urine, and tissue samples [6, 8]. Matalon soon identified an enzyme deficiency that was the cause of Canavan and developed a prenatal test to screen for the deficiency. After this discovery, several nonprofit groups began to promote Canavan disease testing.

In a second stage of research supported by Miami's Children's Hospital Research Institute at Miami Children's Hospital (MCH), and using specimens donated by thousands of research participants, Matalon isolated and cloned the gene associated with Canavan. MCH Research Institute subsequently obtained a patent on the gene and related applications, including carrier and prenatal testing [6, 8]. In addition, MCH Research Institute enacted a marketing plan to enforce its intellectual property rights relating the tests. Annual royalties from the patent reached an estimated \$375,000. To enforce its intellectual property rights, MCH Research Institute sent letters to clinical laboratories engaged in testing for Canavan and to the plaintiffs, informing them of the patent and MCH's intent to enforce the patent by charging a

royalty fee of \$12.50 per test [6, 8]. These letters informed Greenberg and others for the first time of MCH's intent to earn royalties from screening for Canavan [6, 8].

Greenberg and others filed a lawsuit in 2002 against Matalon, MCH, and MCH Research Institute, claiming that the defendants had a continuing duty of informed consent to disclose any information that might influence the prospective subjects' decision to participate in the research [8]. Defendants breached this duty, Greenberg argued, when they failed to disclose the intent to patent the Canavan gene for their own economic benefit and by misrepresenting the research purpose on the written consent forms [8]. Plaintiffs alleged that they would have refused to participate in the research had they known of MCH's true intention to commercialize the genetic material and related testing [8].

While the court recognized that a medical researcher owes research participants a duty of informed consent, it declined to extend this duty to cover disclosure of a researcher's economic interests [7]. The court noted in a footnote that the *AMA Code of Medical Ethics* required disclosure of a commercial interest, yet disregarded this opinion because it was enacted after the defendants' research had begun [3, 8]. The court reasoned that such a duty of informed consent would have a pernicious effect on medical research, in that "it would give each donor complete control over how medical research is used and who benefits from that research" [8]. Further, as a practical matter, retroactively imposing such a duty would "chill medical research," as it would force researchers to constantly evaluate whether a "discloseable event" had occurred [8].

Moreover, the court found as it had in *Moore* that a research product developed from human tissue is factually and legally distinct from the original excised tissue, such that a tissue specimen becomes the property of the researcher and thus prevents the donor from asserting rights in the resulting patent or commercial product [2]. Because the materials were voluntarily donated without a contemporaneous expectation of return, Greenberg and others had no acknowledged property interest in body tissue and genetic matter they had donated, even though commercial benefit accrued as a result [2, 6-8]. This holding was reaffirmed several years later in *Washington University v. Catalona*.

Washington University v. Catalona

In *Washington University v. Catalona*, an internationally known prostate cancer surgeon and researcher, William Catalona, at Washington University (WU) began asking patients to let him use for research the tissue removed during prostate surgery and other biologic samples [9]. Research participants were asked to sign one of various consent forms which included language: (1) acknowledging that the donor was making a "free and generous gift" of tissue to research that may benefit society, and (2) waiving ownership rights in the donated tissue or any medical or scientific product that resulted from research with the donated tissue [10]. All forms provided for patients' withdrawal from the research at will, a right also supported by the Uniform Anatomical Gift Act [9].

WU's biorepository amassed more than 30,000 tissue samples, 3,500 of which came from Catalonia's patients [9]. WU considered the tissue samples not only a resource for prostate cancer advances, but also a source of capital for the university [9]. When Catalonia wished to transfer 2,000 of the samples to a private laboratory for research, WU objected, noting that Catalonia would essentially be appropriating materials "worth nearly \$100,000 to the University" [9].

As the conflict escalated, Catalonia left WU for a position at Northwestern University School of Medicine [9]. He informed his patients of his transfer and asked for permission to transfer their samples to Northwestern [9]. Six thousand patients consented to the transfer [9]. In response, WU both refused to authorize the transfer of samples and sued Catalonia to enforce its refusal, claiming it owned the samples [9].

A group of patients added as necessary parties to the lawsuit claimed that they owned their tissue samples and advocated for their transfer to Northwestern to effectuate their original intent of having Catalonia perform prostate cancer research [9]. The patients argued that Catalonia's actions in transferring universities should not affect their ownership rights [9]. They argued that they donated to Catalonia's prostate cancer research, not for the university to sell the samples to the highest bidder [9]. WU responded that the patients lacked ownership rights to the tissue, since the tissue was a gift to the university [9, 10]. Though the participants retained the right under federal law to withdraw from research and have their samples destroyed, the university argued, they did not have the right to direct and control use of the samples [9].

The Eighth Circuit Court of Appeals held that individuals who donate biospecimens for research purposes *do not* retain ownership interest that would allow them to direct or authorize the transfer of those materials to a third party.

In this case, the research subjects had made informed and voluntary decisions to participate in cancer research, and had donated their biological materials to WU as valid gifts [10]. This voluntary transfer of tissue and blood samples to WU demonstrated that the university owned the biological samples [10]. Whatever rights or interests the research subjects retained following their donation of biological materials, the right to direct or authorize the transfer of their biological materials from WU to another entity was not one of them [10].

The foregoing cases demonstrate that, while individuals have the right to donate bodily tissues for research purposes, the right to own and control use of donated tissues vanishes once those tissues leave the body. The loss of ownership rights means loss of any claim to commercial benefit gained from cell lines or other commercial products derived from research on the donor's tissues. According to the *AMA Code of Medical Ethics*, however, potential commercial applications must be disclosed to a donor before a profit is realized on products developed from

commercial materials [3]. Only with this knowledge can a donor truly make an autonomous decision to donate or not to donate his tissues.

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POLICY FORUM

Autonomy and Exception from Informed-Consent Research

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The well-recorded historical abuse of biomedical research subjects around the world has led to a lasting distrust of the research system [1]. For this reason, it is usually considered obligatory to acquire informed consent for research studies. The international research community strongly condemns any disregard for proper consenting processes [1]. Because of this requirement, vital emergency medicine (EM) research is hampered by urgent health needs that render patients unable to consent for studies. This has led to a relative dearth of research for emergency treatments.

Aware of the need for EM research and the impossibility of obtaining full informed consent from all patients in emergency situations, the Food and Drug Administration (FDA) developed the Exception From Informed Consent (EFIC) policy in 1996 [2]. EFIC allows research in certain life-threatening situations without the expectation that consent will be obtained prior to beginning study procedures. Several adult EFIC trials have been completed to date, the most famous of which led to the approval of the life-saving automated external defibrillator [3-5]. To safeguard EFIC subjects and respect their autonomy, the FDA requires protective measures not present in nonexempt research studies before and during the EFIC study. Despite these protections, some argue that the EFIC methods and protections have not been studied well enough and that there are no quantifiable outcome measures to demonstrate the efficacy of these FDA protections [6]. Thus, EFIC detractors say, patient autonomy may be at risk.

With the first U.S. pediatric EFIC studies currently underway, EFIC policy has recently been extended to include some of the most vulnerable members of society [7, 8]. Here, we consider whether the extra protective measures required by the FDA successfully alleviate existing concerns about conducting research in the absence of informed consent and examine whether the EFIC policy does, in fact, further compromise the autonomy of ER patients with life-threatening illnesses.

Regulation of EFIC Research

Informed-consent processes, which allow patients to discuss significant details of their involvement in a study with the research team before consenting to take part, have become standard practice in the United States and other countries. The FDA's exemption from informed-consent policy, by definition, allows research to be conducted on patients who have not been asked for consent, taking away their established right as autonomous individuals to involve themselves, or not, in medical

research. We believe that EFIC policy does not represent a laissez-faire attitude to research and informed consent but that it acknowledges the necessity of EM research and creates a way of conducting such research while respecting the prospective participant as an autonomous subject [2].

The FDA attempts to assuage public concern about violations of individuals' autonomy through the EFIC by employing strict regulations. First, the EFIC may only be used for studying treatments for life-threatening health problems. These are defined by the FDA and include health conditions that pose a significant risk of patient mortality and morbidity. Next, there must be a possibility for direct benefit to the participant—a demand that is absent in traditional drug-versus-placebo studies. EFIC investigators must also carry out public disclosure and community consultation and offer the community opportunities to object and opt out. Through public disclosure, study information is disseminated to the public before, during, and after the research has taken place. It must include contact information for the research team and provide ways for people to object or opt out of the study. Enrolled study subjects must also be given the opportunity to opt out once they or their guardian have been informed about the study. Community consultation engages the community and study team in two-way discussions about the proposed research. It is only when all of these activities are reviewed and approved by local institutional review boards (IRBs) that clinical EFIC research can begin [2].

These EFIC protections do not act as a proxy for or replace informed consent. Instead, they enable investigators to gain important community, cultural, and personal insights about the research and study population that may otherwise be overlooked [9]. Despite the potential benefits, public disclosure and community consultation have been cited as the most difficult aspects of the EFIC process [9, 10]. Current research shows no consensus about what methods qualify as effective community consultation, and, even more importantly, there is no standard definition for what constitutes a complete and adequate community consultation process [9, 11, 12]. In light of this critique, we must agree that community consultation and public disclosure may not in their current forms protect patients in the ER in the way they are intended [6]. Thus, the inclusion of these protections in EFIC policy call for significantly more thought and research.

Does EFIC Compromise Autonomy of ER Patients?

This concern, however, distracts from the more fundamental ethical question: do these patients have any autonomy to lose? The gravely ill patients who are brought to emergency rooms, both adult and pediatric, rarely have the capacity for fully autonomous decision making. The physician has little or no time to discuss treatment options with patients or their family members. Patients must trust the doctor to pursue the best course of action without delay. EFIC research into life-threatening conditions may not bring any further loss of autonomy because emergency care already deprives patients of the autonomy they might enjoy in other medical settings. Thus, EFIC research offers a chance to discover the best treatment for life-

threatening situations while reducing a patient's autonomy no more than the emergency encounter does by its very nature.

Patient autonomy should not be the only consideration in EM research. EFIC research accommodates reduced autonomy for the sake of other vital rewards, i.e., knowledge of the best life-saving interventions. Whilst involvement in medical research often carries risks beyond those inherent in clinical care, that claim cannot be made here. Current treatments for life-threatening illnesses are not born of gold-standard investigations but are extrapolated from related conditions, (often less severe), or related populations (e.g., pediatric treatments based on adult-only research). This lack of clinical data confers the same risk on the dying patient enrolled in an EFIC study as on un-enrolled patients. As Chamberlain et al. note,

As a nation, we are faced with an ethical choice: we can choose to allow every emergency encounter to be an uncontrolled experiment at the hands of the individual physician, and hence fail to advance the science, or we can choose to enroll patients in a systematic manner into rigorously controlled clinical trials with well-regulated treatment arms and safety monitoring aimed at determining the best treatments [13].

EFIC research creates a scientific basis for treatments of life-threatening conditions. Therefore the ethical query is not whether we should proceed with EFIC or not, but why we are not conducting more. The benefit for society, as well as the potential benefit for the patient, must override concerns about reduced autonomy. It is under this premise that EFIC-EM research should continue while increasing awareness of its importance in medical and lay communities.

Conclusion

The EFIC is a federally mandated process that facilitates investigation of specific, life-threatening medical emergencies without first expecting researchers to obtain the usual informed consent. Many criticize EFIC policy for compromising patients' exercise of autonomy. Extra protections for research subjects in the form of community consultation, public disclosure, ability to opt out, and the possibility of benefit to the patient are unique to research under EFIC. While these protections cannot act as a surrogate for autonomy, they may have a positive impact on the development of research using EFIC methods, but further research on these protections is needed.

If we fully understand the EFIC concept, we must accept that it does not reduce autonomy but merely reflects the already reduced autonomy of patients in the acute emergency setting. Society must also recognize that other ethical considerations might override autonomy when conducting necessary EM research using EFIC. It is then that, despite diminished autonomy of most emergency patients, EFIC studies represent an appropriate ethical path for emergency medicine research.

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MEDICINE AND SOCIETY

How Autonomous Is Medical Decision Making?

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Medical clinicians are bound by a universal ethical code first encapsulated within the so-called Hippocratic Oath and enshrined in professional codes of ethics in all specialties. The vast majority of patients that a clinician encounters over the course of his or her career will share the clinician's commitment to the moral ideals which underlie and derive from the oath. Most will agree, for example, that minimizing their suffering and preventing avoidable death are of paramount importance. There are exceptions to this general phenomenon, however, and these instances raise fundamental questions for the ethical regulation of clinical practice.

The moral ideals of the Hippocratic Oath are not universally shared and espoused. For some patients, physical suffering or even dying from a medically preventable death is not the worst thing that can happen. Some patients have refused to consent to rudimentary medical treatment in full knowledge that the inevitable consequence of their refusal would be their premature and, in clinical terms, unnecessary death. The most commonly cited example of this phenomenon is the Jehovah's Witness refusal to receive a blood transfusion. U.S. courts have tended to uphold decisions made by competent adult patients in such instances and have denied medical authorities' requests to administer treatment against patients' wishes.

Thus, clinicians have been prevented from saving lives in the name of patient autonomy [1]. The application of life-saving medical expertise is refused in the name of patients' commitment to the tenets of their religion, recognizing the will of their God. While the literature in this area of medical ethics might suggest otherwise, Jehovah's Witnesses by no means exhaust the list of religious and cultural communities who have, or are likely to, refuse medical treatment on moral grounds. The Church of Christ, Scientist has long prohibited the use of vaccinations and inoculations amongst its members. Similarly, a strict adherence to vegan ideals is incompatible with receiving medical treatment that involves or has fundamentally benefited from xenotransplantation technology.

Many societies are increasingly multicultural in character, an inevitable consequence of which is the exposure of medical clinicians to a diverse range of ethical ideals that are, in various ways, incompatible with the secular ethos upon which Western biomedical clinical practice is based. In the United States, one might cite Buddhist, Shinto, Confucian, Hindu, and even Muslim ideals that prohibit such practices as the transplantation of religiously sacred or taboo organs amongst their adherents. The more ethnically and religiously diverse a society becomes, the greater the likelihood

its medical clinicians will confront ethical ideals and commitments that restrict or prevent them from minimising harm and preventing unnecessary death [2].

Determining Patient Autonomy

The more severe the likely medical consequences of such patient refusals, the greater the challenge to clinicians. When refusals are not grounded in beliefs of a recognised religion, clinicians generally request that a determination of the patient's mental competence be made. Patients who have cognitive deficits are likely to be deemed incompetent to determine what is in their best interests and incapable of exercising genuine autonomy. Likewise, a patient with a history of schizophrenia, admitted to a hospital with a life-threatening but curable condition, who refuses treatment on the grounds that the voices in his head are telling him to reject the clinician's recommendations is unlikely to avoid treatment. Another patient with a similar condition, however, who refuses treatment on the grounds that his religion and his God strictly forbid any such action is, all things being equal, likely to prevail, even if this results in his death. Devout atheists and secularists might question whether a genuine distinction can be made between the clinically incompetent and the more conventionally irrational believer in a recognized religion. Medical ethicists would reply that the criterion for determining a patient's decision-making capacity is not so much what the patient avows and espouses but how he came to hold the commitments and beliefs he does: form prevails over the substance in this regard.

Conventional medical ethics tends to accept this source-based distinction and avoids challenging the ideals and practices of communities that in some cases have existed for millennia. This position takes its bearings from commitment to the thoroughly reasonable ideal of respecting religious and cultural beliefs that differ from one's own. A desire to avoid religious and cultural intolerance is a basic expectation of all citizens, irrespective of whether they happen to be medical clinicians or patients. But respecting another's religious and cultural beliefs does not, by itself, compel us to accept that those beliefs have been examined and are autonomously espoused. After all, we come to hold beliefs in a multitude of ways, not all of which necessarily satisfy philosophic criteria for being autonomous—that is, not all are fully informed and uncoerced. In fact, when it comes to some of our deepest and most fundamentally avowed beliefs and commitments, there are good reasons to question whether genuine autonomy has played a sufficient role.

The key criterion for the clinical determination of patient autonomy is the mental competence test, familiar to all practicing clinicians. As it stands, this criterion is straight-forward and uncontroversial enough. But from a more robust philosophical perspective, this test, while necessary, is not sufficient. To complete the picture we must add the condition of the individual's having the opportunity to exercise choice, which entails the existence of legitimate, known options. To exercise autonomy, one must have more than one option from which to choose. When this criterion—existence of known, available options—is combined with the criterion of sufficient mental competence; applying the principle of respect for patient autonomy to

patients who refuse treatment on grounds of their deepest ethical commitments gets philosophically complex.

Many religious and secular ethical commitments require fundamental and unequivocal adherence to a set of established tenets of faith on the part of all who wish to be recognised members of the faith community. To medical clinicians this set of required beliefs is most evident in those patients for whom death of the body is not the worst thing that can happen. In these instances patients might be said to have a *formal* choice, in so far as they can either repudiate their beliefs and undergo the treatment or comply with their beliefs and suffer the consequences. But viewing this situation in these terms undervalues and fails to fully appreciate what it means to espouse such fundamental beliefs.

On the other hand, it would be a mistake to dismiss such beliefs as *necessarily* incompatible with the exercise of autonomy, which must extend to include the avowal of both the deepest and even the most trivial beliefs and commitments. A commitment to morally absolutist beliefs should not be dismissed as necessarily binding the individual who adheres to them and thereby denying that individual's autonomy. Choice remains the principal element of acting autonomously, and therein lies the potential for re-evaluating the conventional bioethical understanding of patient autonomy.

Doubting the Determination

Many of the more devout amongst us do indeed choose to recognise the authority of a moral or cultural tradition. We can say that such individuals have chosen to enter into some community that is willing to accept them. The same cannot be said so easily of those born into a particular way of life who know little or nothing of the beliefs, traditions, and practices that constitute fundamental aspects of their adherents' identities. As some philosophers and social theorists have argued, certain forms of cultural identity can constitute their adherents' identities and sense of self [3]. In these instances, distinguishing the autonomous element of an individual's compliance with values and ideals that prevent life-saving medical treatment is a difficult task and one that lies beyond the expertise of medical and legal professionals.

Seeking to avoid allegations of religious and cultural intolerance, some medical ethicists and legal philosophers argue that everyone has an opportunity to leave his or her community and that a continuing adherence to a particular community, irrespective of how one came to be a member in the first place, may be construed as sufficient evidence of an individual's autonomous decision to accept its rules and practices, even if complying with them might result in a medically preventable death. The so-called 'right of exit' resolution is in some instances naive and complacent [4]. For many reasons an individual might find it extremely difficult, if not impossible, to repudiate his or her community—lack of sufficient resources, for example, geographic isolation, or the individual's inability to imagine himself or herself being any other way than that prescribed by the community. The more deeply an individual

is formed by religion or culture, the more difficult it will be to recreate his or her identity in an alternative existential setting. The depth of an individual's integration within some communities and the absoluteness of that community's ethical prescriptions can severely restrict the individual's capacity to exercise choice, particularly in matters of life and death. In cases such as these, an individual may have little real choice but to comply with a fundamental religious tenet, even if this might cause great suffering or even a premature death.

Lessons to Learn

In practice, the bioethical ideal of respect for patient autonomy is far messier than medical ethics textbooks suggest. One of the most fraught areas of the relationship between clinician and patient in this regard concerns a clash of ethical values that prevent clinicians from minimising suffering and preventing death. Typically, this conflict is resolved by appeal to the principle of patient autonomy. I have suggested, however, that both the formulation and the application of this principle require closer scrutiny and analysis. I do not, at this point, propose a clear solution. Clinicians should not simply ignore patients' beliefs because they are informed by deep and uncompromising religious or cultural commitments that differ from those underlying much professional medical ethics. On the other hand, the presumption that, subject to satisfying a mental competence test, such patients are to be simply considered as exercising autonomy is based upon a degree of philosophical complacency and sociological naivety. Recognising the problem is the first step towards developing an effective remedy.

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David Segal, PhD, is assistant professor in the College of Health and Public Affairs at the University of Central Florida in Orlando. He has taught health science courses for over 15 years. His current research focuses on the use of adaptive, collaborative, and synchronous gaming and simulation technologies to improve the learner's decision-making skills and performance assessment. Dr. Segal has expertise in medical informatics and dynamic visualization programming for online collaboration and decision support.

Rachel Stanley, MD, is an attending pediatric emergency physician for the University of Michigan Emergency Department in Ann Arbor. She attended medical school at the Royal College of Surgeons, Ireland, and trained as a pediatrician at the University of Connecticut and as a pediatric emergency physician at the Children's Hospital in Boston. Her research interests include randomized control trials of emergency interventions for children and the exception from informed consent.

Ryan C. VanWoerkom is entering his fourth year of medical school at the University of Utah where he has co-written three successful grants. He is currently serving as the student representative to the AMA-Medical Student Section on behalf of the American College of Physicians-Council of Student Members and as chair of the Committee on Bioethics and Humanities. His plans include residency training in internal medicine followed by cardiology training.

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