

Virtual Mentor
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Establishing the Boundaries of Informed Consent

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FROM THE EDITOR

The Less-Told Stories of Informed Consent

So much is written about informed consent—from how students and residents are taught to “consent” a patient (ugh) to the challenging of patients’ decision-making capability should they refuse recommended treatment. Often missing from these war(d) stories is a discussion of when in the course of ongoing patient care consent to treatment should be renegotiated. When a patient comes to the clinic or office, one assumes that he or she agrees to be asked questions about health history and to be examined. At what point in the care of that patient, though, is consent needed for a specific test or treatment intervention? And if special consent *is* required, for a lumbar puncture, say, must it be written, or will an oral consent, a nod of the head, or just the absence of a refusal suffice?

In this issue of *Virtual Mentor*, we examine the border between implicit, assumed consent and the place where explicit patient consent must be secured. We also examine two separate but equally important questions: how much information satisfies the legal and ethical stipulations that consent be “informed” and how convinced are we that the consent patients offer truly represents their understanding and acceptance of the diagnosis and treatment options the physician has presented?

Each of the four clinical cases explores a situation in which a physician confronts a serious consent question. Would a walk-in patient at a free clinic bolt if a doctor told him of the reporting requirements that go along with his HIV test? Or can the doctor withhold that information, for the patient’s good or the good of a third party—namely, the patient’s life partner? A second case places a physician in an emergency department when an intoxicated patient with head trauma refuses to cooperate with tests or scans. When is it ethical to override such a patient’s refusal of a head scan? Again, this is a serious ethical problem for the physician, with possible liability exposure as well. As a complement to this case, the clinical pearl details the classification and medical evaluation for traumatic brain injury.

The third case involves a teen whose cancer has returned. Treatment options that have toxic side effects and represent the patient’s best chance for cure are tough enough to explain to an adult, and mature minors merit special consideration. Can the teenager refuse treatment? Should the doctor downplay the effects of a therapy in an effort to convince the teen to begin treatment? Finally, recognizing that most physicians face the physical exam encounter daily, our fourth case explores the line between assumed and explicit consent during sensitive aspects of the routine physical.

Teaching about informed consent is a key to improving the quality of patient consent. This month's medical education article looks at that subject closely. How do subtle differences in the way difficult choices are framed influence the likelihood that consent will be given—or refused? Competence to consent to treatment is not always self-evident. Paul Appelbaum's classic article on that topic is the target of our journal discussion. Law has developed around consent controversies and has helped define the doctor's task of explaining treatment options to patients. As the health law article explains, the classic case of *Canterbury v. Spence* based its guidelines for the information patients should receive on "reasonable person" and "reasonable physician" standards—what would a reasonable person want to know? What would a reasonable physician consider "material" to the patient's decision?

Sometimes those who most need protection cannot consent for themselves to medical treatment or research. Wards of the state are a prime example of this sort of vulnerable population, and our policy forum article examines the importance of appointing effective guardians to watch out for these minors' rights.

The medicine and society column takes on the real question at the heart of many of these boundary cases of informed consent at work: Does the informed consent process—as currently practiced in the U.S.—truly elicit patient preferences, or does it merely allow patients to select which of the physician-determined options is most acceptable (or least unacceptable) to them?

Finally, we'd like to thank Ankit Shah, MD, JD, for suggesting the month's topic and working on the issue's case development and article outline for us.

Sincerely,

Philip Perry, MSJ
Allison Grady
Faith Lagay, PhD
Editors, *Virtual Mentor*

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CLINICAL CASE

Informed Refusal in the Emergency Department...Is It Really Informed?

Commentary by Matthew R. Lewin, MD, PhD

Dr. Padgett was the attending physician during the night shift in an urban hospital emergency department. He had one resident and one intern working with him. Over the span of 4 hours, he had seen 17 patients. There were 21 patients still in the waiting room when an ambulance arrived carrying Ms. Burton, a 38-year-old professional woman, who had been drinking alone. As she exited the bar, bystanders witnessed her fall from standing height, hitting her forehead. The EMS run sheet said it was uncertain whether she'd had any loss of consciousness. Witnesses could only attest to the fact that, if she had lost consciousness, it was a brief loss because they heard her muttering expletives on the sidewalk seconds later. Her prehospital fingerstick glucose was normal. She arrived in the emergency department on a spine board, wearing a cervical collar, and very angry about being taken to the hospital against her will.

Ms. Burton was perfectly oriented, alert, intoxicated on alcohol, and combative with staff, refusing care. She had signs of a fall—a contusion and abrasion to her left orbit and forehead. She growled her displeasure as Dr. Padgett checked her vital signs, which were unremarkable except for a modest elevated blood pressure and tachycardia. To the extent that a neurological exam could be performed, it was nonfocal.

After the exam, when Dr. Padgett told Ms. Burton that he was ordering a CT scan of her head to check for intracranial bleeding, she refused. Dr. Padgett began explaining the reasons for his decision and the consequences of bleeding in her skull, but Ms. Burton was having none of it, claiming that she couldn't afford those tests. She removed the IV from her arm, flung it in the direction of Dr. Padgett, and attempted to clamber over the railings of the gurney only to be restrained by nurses and staff concerned about her fall risk.

Ms. Burton admitted, by now, to having a headache at the site of the forehead contusion, but said she'd go home and come back immediately if she "got worse." She steadfastly denied depression, suicidal ideation, or even alcohol abuse, simply stating that she only drank on weekends, that she was a professional, and that this had happened "many times before." She refused to allow phone calls to family, friends, or co-workers claiming that this was "none of their business."

Commentary

Let's see. I have a combative patient who may or may not have a significant brain injury and a busy, understaffed emergency department. The patient appears to have decision-making capacity, but has trauma above the clavicle, a headache despite intoxication, and is irritable and impatient—all classic signs of acute brain injury. We haven't even considered other elements of the differential diagnosis for these signs, which include electrolyte abnormalities, arrhythmias, cerebellar dysfunction, normal pressure hydrocephalus, Wernicke's encephalopathy, toxic alcohols, and infection. Ms. Burton may have a second diagnosis that is equally important and potentially discoverable simply because she fell.

I have several options. Option 1: Try to reason with her and then let her go at her own peril (assuming she can walk). I might ask her if she would accept the CT scan if she weren't charged for it. If the answer is "No, let me go," that would call her judgment into question because she is contradicting her stated reason for refusing care. In that case, I could put her on a legal, medical hold for being a danger to herself—a weak argument to an informed consent "absolutist," for whom the patient's reasons for refusing don't really matter as long as she has demonstrated the ability to reason and is oriented. I could also call a psychiatrist to assess her decision-making capacity, but the psychiatrist will confront the same problem I have of sorting out the irritability from acute brain injury, something I am far more likely to have seen and with greater frequency than the average psychiatrist. Nevertheless, the patient might sober up even before the psychiatrist's assessment and benefit from the consultation that would at least touch on substance abuse.

I am completely opposed to this two-part option—letting the patient check out against medical advice or seeking a psychiatric consult. We don't have the time or resources to wait for a consultant when the patient isn't even medically cleared for psychiatric assessment. The patient will receive referrals for psychiatric and substance abuse counseling, whether she sees a psychiatrist tonight or not. If she leaves the department against medical advice, she will still be responsible for the ambulance bill, facility and nursing charges, and the medical screening exam by Dr. Padgett. Although the hospital will be willing to accept some type of payment schedule, it will be hard for Ms. Burton to argue that she is being charged for care that was unreasonable, considering her risk factors for significant brain injury.

Option 2: Do nothing except observe her. Considering her determination to leave, this would require commitment from the staff to keep her in her gurney whether or not she was on a medical hold. Restrained patients have to be monitored at all times, and intoxicated patients can't be walking around the emergency department since they are fall risks, something this patient has already proven. I could call the nursing supervisor to see if there are staff members able and willing to float down to the ED to help out. Alternatively, there might be security staff credentialed as sitters. If she sobers up, can walk, and still has decision-making capacity, then it should be safe for her to go home, even if she lives alone. This approach is commonly referred to as "metabolizing to freedom." Given that most brain injuries are not, in fact,

neurosurgical emergencies, even when there is blood, a respectable minority would argue that it is not even important to identify all bleeds—especially if the patient’s mentation clears.

My failure to mention obtaining a blood alcohol level (BAL) until now is deliberate. This patient is a binge drinker, and there is no way to predict the rate at which she clears alcohol from her system. Furthermore, BAL does not predict decision-making capacity. Although a lay jury might acquit me for acting without the patient’s consent if I found a high BAL, the science does not. Many people have very high intellectual function with very high concentrations of alcohol in their blood, making any decision about her capacity based on the BAL a falsely reassuring prejudice.

This option is more appealing in the sense that the patient is potentially spared the expense of the test she says she doesn’t want, but we still get to observe her. If her behavior improves at a rate within some reasonable range for alcohol intoxication, she can be reexamined and released. The problem is that she is actively trying to “escape,” and it is not clear whether her attempts are prompted by a quite rational fear of the bill she will receive or whether she is suffering from an injured brain. Bills from the radiology department will be much more difficult to negotiate than mine and the emergency department’s facility and nursing fees. I can certainly cancel my pro-fee and reduce the ED charges by advocating for the patient, but I cannot ask the radiology department to cut their charges for the test I order. The patient could pay the negotiated fees over an extended period of time, if she needs further financial assistance. I routinely write letters on behalf of self-insured patients. Why should they pay the “billed” rates that are discounted to third-party payers and government programs such as Medicaid? In my experience, the hospitals are happy to collect less in exchange for less trouble.

Option 3: Restrain, sedate and get a CT scan of Ms. Burton’s brain. This option places the interests of the emergency department and its patients as a whole over the immediate interests of the individual patient. This patient is a distraction to my staff and to me that comes at the expense of others’ care and safety. Acting on this option resolves the medical questions quickly, spares resources (e.g., staff and bed) for the benefit of others, and most safely returns the patient to her home or the street—but it completely ignores the patient’s stated wishes. If her brain CT is normal, she can refuse imaging of her cervical spine (heretofore neglected in the discussion, but definitely indicated). She can remain in a cervical collar until the dust settles. If she has a clinically significant fracture, that isn’t likely to be the reason she is agitated. If her CT scan is positive, then we would proceed with cervical spine imaging and not ask her permission.

Dr. Padgett has been “on” for at least 4 hours and probably has no more than 4 to 8 hours to resolve the case of Ms. Burton before he will have to sign her out to the next attending. Sign-out is notoriously dangerous under the best of circumstances, and Dr. Padgett will be signing out a patient with altered mental status to the next attending, Dr. M’Fleur, who did not see the patient at presentation or during any of the repeat

neurological examinations. As far as Dr. M’Fleur is concerned, this is a new patient with a new baseline. If Dr. Padgett elected to use chemical or physical restraints or both, Ms. Burton’s neurological examination could be compromised by sedation or she may simply be hung-over and sleepy. How is Dr. M’Fleur supposed to assess the patient or have any idea about the rate at which Ms. Burton should be improving? Dr. M’Fleur is inheriting a high-risk situation, even if the patient hadn’t refused care, and Dr. Padgett was merely following the “metabolize to freedom” strategy.

As a general rule, I have a lower threshold for CT scanning if I am signing out an intoxicated patient. It is not appropriate to risk patient safety and foist diagnostic dilemmas or my clinical style onto the new team.

Dr. Padgett’s medical decision making has to account for his presence or absence at the time he anticipates Ms. Burton’s disposition home or admission for observation by the neurosurgical or medicine services. Supposing the ED is so busy or Dr. Padgett is so tied up with other patients that he cannot return to the bedside for reassessment of Ms. Burton, resulting in a potentially dangerous delay in her care? Post hoc critiques of his care will call his judgment into question: Wasn’t it obvious that she had a bleed?

Scarce Resources

Allocation of scarce resources must also be considered. Every decision the physician makes about one patient has a consequence for every other patient in the emergency department. Every action, procedure, phone call or order consumes nursing time, clerical time, adds to the physician’s “to do” list, and, ultimately, affects patient flow through the department. Thus, practical considerations inevitably come into play with any patient—especially challenging ones like Ms. Burton.

Much has been written about the differences between emergency medicine and primary care practice. Among many factors, emergency department personnel do not usually know the patient or their families; the patient has experienced an acute change in health; decisions are made quickly and independent of outside information or consultation with others who do know the patient; the physician is working in an open and uncontrolled environment; and anxiety, pain, alcohol, and altered mental status are frequent occurrences, typically with a high frequency of serious, underlying pathology. If there is no way for the emergency physician to buy enough time to make a safe decision for the patient or avoid compromising the safety of others, the physician must make a decision which is, ideally: (1) based on impartiality, (2) universalizable to other situations, and (3) what others would likely find justifiable given the same set of circumstances. This is a sort of formalized “golden rule.”

I don’t know what Dr. Padgett should do, but I know what I would do, absent the luxury of time, personnel, and a family member of Ms. Burton whom I could contact. I would sedate or restrain Ms. Burton, or both, image her brain, and hope it is normal. She would be discharged with written instructions, referrals, and a

personal note from me that if she cannot pay the full bill, I will advocate for significant reduction. After that, it is her choice and responsibility to take me up on my offer to write a letter on her behalf. She is free to file a complaint against me, which might help reduce her bill even further or erase it if she is sufficiently resourceful.

Given more resources or time I would observe her. Given a responsible family member or close friend who says she is “always this way,” when intoxicated, and if she has not indicated that she has any intention to harm herself, I would honor her wishes without much hesitation.

Did I mention that I saw this patient last night...?

Matthew R. Lewin, MD, PhD, is an assistant professor of emergency medicine in the Department of Emergency Medicine at the University of California, San Francisco. His research interests include basic respiratory physiology, pharmacology, and the practice of general emergency medicine.

Related in VM

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CLINICAL CASE

Informed Consent: When and Why

Commentary by Erin A. Egan, MD, JD

Dr. Wood opened the door to the exam room and smiled at Mrs. Robertson who was waiting in her patient gown. “Hi, Mrs. R, I’d like to ask a favor. Del, here, is on a family medicine rotation and, if it’s OK with you, he’ll assist with your exam today. Is that alright with you?”

“Sure,” replied Mrs. Robertson, “I’m all for medical education.”

“Thank you,” said Del.

“Why don’t you begin by checking Mrs. Robertson’s vitals,” instructed Dr. Wood. After noting these results, Dr. Wood took over the physical, asking questions and sharing a few observations with Del. Dr. Wood then asked Mrs. Robertson to undo her gown and he proceeded to conduct a breast exam by raising her arm, pressing on her breast to check for lumps, and looking carefully at the nipples for signs of discharge. After examining both breasts and palpating Mrs. Robertson’s liver and ovaries, Dr. Wood asked Del to step outside and send the nurse in, so he could collect a Pap smear.

After Mrs. Robertson left, Del said, “This is my first rotation, and one thing I’ve been wondering, Dr. Wood, is do we just do all of the standard aspects of the physical on our patients without asking? Like the breast exam, for instance. Because I’m so young and everything, I feel as though I should ask permission, but you just went right ahead. She didn’t object so I guess it’s OK, but is that routine? Where is the line where I have to ask or get consent? Did you ask consent to do the Pap, or is it all assumed consent?”

Dr. Wood considered Del’s question. “That’s a really good point. Mrs. Robertson has been my patient for a while, for one thing. But still, I don’t recall ever having my professors tell me specifically what are or are not the trigger events for a consent—verbal or otherwise—in a routine check-up. I can’t remember a lot of articles on that, and I’ve been in practice for quite a while.”

Commentary

What level of consent is required for a patient-physician encounter? There is no fixed answer. The threshold varies with each patient, each physician, the type of interaction, and the risks and benefits that intervention presents. That being said, there are some general rules about when to obtain consent. Our case deals with

consent in the context of an interview and examination, not the invasive procedure setting that usually sparks informed consent concerns. Nevertheless patients deserve to be told about and agree to all aspects of proposed care, regardless of whether they are undergoing a procedure or having a conversation. Often consent is tacit—a patient’s presence and cooperation with the interview and the exam are taken to mean that he or she consents to the proceedings. If the patient is likely to have made assumptions about the interaction that are untrue, the physician should correct those misconceptions. A clear example of this is described in the case—a patient should be made aware that a medical student is involved in her care and should be allowed to consent to or refuse the student’s participation with special attention given to sensitive aspects of the history and examination [1, 2].

The basis for the informed consent requirement is the principle of respect for personal autonomy [3]. The ethical responsibility to respect the autonomy of a person is fulfilled by telling a patient what he or she needs to know to make informed decisions about treatment options. Clinical judgment is involved here; what is the balance between too little information and too much? Legal guidance for adequacy of disclosure for informed consent can be thought of as providing either what a reasonable patient would want to know or what a reasonable physician would disclose [4]. The exact standards vary by state, but these guidelines can help physicians determine when they need to get a patient’s consent and what they should disclose.

Small variations in details can change the informed consent requirement. It is probably safe to assume that a patient who comes to a cardiologist expects to have a heart exam, so the physician need not solicit “consent,” but he or she should engage in the good clinical practice of telling the patient what he or she is doing throughout the examination. Imagine that our cardiologist believes that a breast exam could be relevant to making an accurate diagnosis. It is reasonable to anticipate that the patient would want to be informed of that exam and allowed to ask questions before it is performed since this may exceed the scope of what the patient expects and involves a particularly sensitive area of the body. An informal (not written) discussion explaining why the breast exam is necessary, providing information to the patient based on her concerns, and obtaining verbal assent from the patient after this explanation may be “consent” enough. Described in this way, consent sounds like a laborious practice that requires so much time that it will limit the number of patients a physician can see. Actually discussing a procedure or exam takes as much time as it took to read this. Often the need for a formal discussion doesn’t come up, but is more a part of the exchange that occurs while care is provided and received.

Getting beyond Broad Consent for Treatment

At the initiation of a health care relationship the patient signs some type of broad consent to being evaluated and treated. Routine, very low-risk procedures are done under this blanket agreement. Small changes that increase risk, encroach on a particularly sensitive subject, or have the potential to have a significant effect on the life of the patient require further discussion between the physician and the patient.

Examples of procedures that require specific discussion are blood testing for HIV (versus routine blood draws); giving blood products (versus giving IV fluids); lumbar puncture (versus venipuncture). The difference between these technically similar procedures is clear: the risks are different, the personal implications are greater, or the level of training and skill needed by the clinician is greater.

Informed consent requires a discussion of risks, benefits, and alternatives with a patient who can understand and react to the information and make choices. Once a course of therapy is initiated, it may be carried out without further consent discussion, assuming that the patient doesn't ask to revisit or revoke assent [5]. Anything that changes the equation of risks, benefits, alternatives, understanding, or ability to make a choice requires returning to the consent process with the patient. If, for example, a patient does not respond well during the course of treatment, and it becomes unlikely that he or she will benefit from the agreed-upon treatment, consent must be discussed because the potential for benefit has changed. If a complication puts a patient at higher risk for further complications with continuing treatment, the patient must decide how to balance this increased risk within his or her own values.

The consent also needs additional clarification whenever an area of special sensitivity becomes involved. In discussions of intensely personal matters, patients deserve to set the parameters of the discussion. Genital exams involve an obvious area of sensitivity, and elements of sexual history are very personal. The patient's desire for privacy should be discussed and respected. If a patient has a particular concern or anxiety that the doctor is aware of, it should be addressed directly during a consent discussion. Finally, a patient has a right to know the level of skill and experience of anyone performing a procedure.

In sum, a solid understanding of the goals of informed consent can guide one's decisions about when it needs to be discussed and what level of disclosure is satisfactory. Respecting a person's right to autonomous decision making defines the boundaries of consent. Good clinical practice and an emphasis on communication as a routine part of any interaction eliminate much of the need to overthink consent in routine situations. It is respectful to introduce everyone in the room and clarify each person's role. It is sound clinical practice to explain what you are doing while you examine a patient and to state what you will need to touch or look at. As situations become more complex and interventions more invasive, the fundamental value that is to be protected is the patient's autonomy. If you are unsure about whether consent is needed, talking to a patient should be the first step. Having discussions about what respect and autonomy mean to them, even briefly, will help you decide how to tailor the care the patient receives to their individual needs and expectations.

Notes and References

1. American Medical Association. Opinion 8.087 Medical student involvement in patient care. *Code of Medical Ethics*. Chicago, IL: American Medical Association; 2008. http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/E-

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2. See the discussion in Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 4th ed. New York, NY: Oxford University Press; 1994:438.
3. Beauchamp, 142-146.
4. Beauchamp, 147-150.
5. For an example of this principle see *Gorab v Zook*, 943 P2d 423 (Colo 1997). This is Colorado case law and not binding in all states, but it explains the legal position that consent for a treatment plan holds for the duration of that treatment plan.

Erin A. Egan, MD, JD, is an assistant professor of medicine at the University of Colorado Denver, a faculty associate with the Center for Bioethics at the University of Colorado Denver (UCD), and a visiting lecturer at the Neiswanger Institute for Bioethics and Health Policy at the Loyola University Stritch School of Medicine in Maywood, Illinois. She serves on the ethics consultation subcommittee, the ethics committee, and the organizational ethics committee at UCD, is the director of quality improvement for the Hospital Medicine Group, and the program director for the Holocaust in Contemporary Bioethics Program.

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CLINICAL CASE

Withholding Information from an Adolescent

Commentary by Libby Brockman and Megan A. Moreno, MD, MEd, MPH

“I get that my cancer’s back,” said Blake, obviously frustrated and eager to leave Dr. Conrad’s office. “So what’s the plan? How tough is it going to be?”

Dr. Conrad answered, “Well, it is a fairly aggressive treatment. I can’t deny that. But you’re 16 now and pretty strong. The side effects are different for everyone; they can range anywhere from mild to harsh. This therapy has worked for a lot of patients and I believe it can work for you. What do you think?”

Just then Blake’s cell phone rang. “I’m stepping out for a second,” he said to Dr. Conrad. “It’s one of my best friends.”

“Sure, go ahead.” Dr. Conrad said and turned to Blake’s parents for some corroboration. They had been over this ground before when Blake’s initial chemo treatments had put his acute lymphoblastic leukemia into remission, giving him several years of normal life.

“I’ve been talking to him about the importance of starting treatment again,” said Blake’s father. “Maybe I didn’t do a good enough job explaining the urgency of it. He says he wants to know what to expect before deciding.”

Blake’s mother also weighed in, “I think he should be the one to make this decision. He asked directly, what does this treatment entail? He doesn’t like it when we hold out on him. He wants to know the truth—and he deserves to be given all of the information straight.”

“This time treatment will consist of not only high doses of chemo but radiation, too. But I don’t want to lay all that on him right now,” said Dr. Conrad. “All I want is for him just to agree to begin the new round of treatments.”

Commentary

During adolescence, teens like Blake typically engage in important developmental tasks such as defining their identities and asserting their independence. This experience has been complicated for Blake by the diagnosis, remission, and return of his cancer. When he is told how aggressive his new treatment will be, Blake appears apprehensive and unsure of whether he wants to proceed with Dr. Conrad’s recommended treatment plan. We immediately wonder whether Blake’s hesitancy is

part of normal adolescence in which he seeks autonomy, or the result of rational thinking that has led him to seriously consider death over painful cancer therapy.

In the case scenario, we learn that Dr. Conrad hasn't been completely forthright with Blake regarding the extent of the treatment plan because he fears Blake will refuse his recommendation. Dr. Conrad appeals to Blake's parents, who are aware that he has withheld information, and admits that his priority is obtaining Blake's assent and beginning therapy; only after Blake begins treatment does Dr. Conrad plan to reveal the full extent of the care plan. Dr. Conrad's approach raises questions about how much disclosure is required when informing a patient and obtaining his or her consent for medical treatment, and whether it is ethical to keep Blake uninformed of the details of his treatment.

We will first address the question of whether Blake has the right to make this medical decision for himself—in other words, is his consent needed to proceed with treatment? While Dr. Conrad strives to involve Blake in the decision-making process, is he required by law to do so? In 1990, the Supreme Court granted adults the right to refuse medical treatment, assuming they are competent to make their own decisions [1]. This right was not extended to children, and today parental consent is still needed for the medical treatment of individuals under the age of 18.

Though most would agree there are cognitive differences between a 7-year-old and a 15-year-old, such distinctions are less discernable between older adolescents. Is an 18-year-old significantly more mature than a 17-year-old? What about a 16-year-old like Blake? The “mature minor” distinction was created to address this issue and allows “a minor to consent to medical treatment if he is found competent enough to make the decision on his own” [2, 3]. Judging the competence of a minor has proven to be quite complicated, and medical literature has questioned the validity of the concept [4]. While Jean Piaget's four-stage model of development proposes that individuals begin to employ mature thinking processes between the ages of 11 and 15, critics are quick to point out that Piaget's developmental stages fail to take into account the social and environmental pressures that can affect an adolescent's decision-making capability [2, 5]. Some studies have shown that 14-year-olds possess the same competency and decision-making skills as adults [6]. Other research claims that adolescents and adults have very different perspectives on the world: adolescents are generally more susceptible to peer pressure, make riskier choices, and tend to focus on immediate rather than long-term consequences [7, 8]. Finally—and importantly—the intense stress of disease can drastically impair one's decision-making abilities, regardless of age.

Moving, then, to Dr. Conrad's strategy for disclosing the details of Blake's treatment plan, both the American Medical Association (AMA) and the American Academy of Pediatrics (AAP) state that physicians have a duty to provide decision makers with all information pertinent to their treatment options, including details about risks, discomforts, side effects, and alternative therapies [9, 10]. There is reason to believe “patients, family members, or other decision makers want to hear the reality of their

situation,” and consequently the AAP declares, “[i]nformation may not be withheld on the grounds that it might cause the patient...to decline a recommended treatment” [9]. Research involving cancer patients has shown that they much prefer their physicians to offer realistic, individualized prognoses [11]. Such open communication fosters a trusting patient-physician relationship, which is imperative for the provision of good health care.

It is clear that these two ethical concerns are inextricably linked. From a legal standpoint, whether or not a physician is required to provide the patient with complete details of a given treatment directly depends upon whether the patient is able to consent to his or her own care. The doctor’s legal obligations are to the decision maker. In this specific case it is unclear whether Blake can be considered a mature minor; there isn’t enough evidence to determine his level of competency. For the sake of argument let us consider the teen before us who has recently learned his cancer has returned. Instead of participating in a discussion of treatment options, he answers his cell phone and leaves the room. Though details of the past discussions between father and son are not provided, Blake’s father may not be at fault for unsuccessfully convincing Blake to begin treatment again—it is quite possible that Blake just isn’t getting it. Based on this limited amount of information, Blake does not seem to fit the profile of a mature minor, in which case Dr. Conrad would not be legally required to obtain Blake’s consent to begin treatment. It is reasonable to conclude, therefore, that Dr. Conrad is not acting *unlawfully* when he withholds details of the treatment plan from Blake and provides them only to the minor’s parents.

Dr. Conrad’s legal obligation can provide a framework for this case, but it is only part of the story. Professional ethical obligations often transcend legal obligations. Ethically, Dr. Conrad must consider what is in his patient’s best interest, not just what is in the decision maker’s best interest. Although Dr. Conrad doesn’t legally *need* Blake’s consent to begin treatment, he should *want* it. There are two main reasons why fully disclosing the treatment plan and obtaining assent for treatment would be in Blake’s best interest. Firstly, doing so will improve Blake’s investment in and compliance with the cancer therapy. Research has shown that patients who understand and assent to their treatment plan are more likely to adhere to it [12]. Given that compliance is a particular problem among adolescent patients, Dr. Conrad should make every effort to obtain Blake’s buy-in to the plan [13].

The second reason why Dr. Conrad should disclose the details to Blake is that failure to do so might threaten the heretofore positive patient-physician relationship. When Blake eventually learns that he wasn’t given the whole story, he may feel betrayed by Dr. Conrad and his parents, which could easily result in a weakening of those important bonds. This deception is unnecessary and may impact Blake’s further investment in his treatment. Therefore, if Dr. Conrad is truly acting in Blake’s best interest, he should *want* and actively seek Blake’s assent; such agreement could improve Blake’s chances of success.

In this case, we recommend that Dr. Conrad be up front with Blake and allow him reasonable time to ponder his options. If Blake persists in his hesitancy, Dr. Conrad can negotiate by offering Blake the option of stopping treatment at any point after its commencement. This plan would highlight for Blake that he and his doctor are actually partners. Allowing this type of negotiation to continue throughout the course of chemotherapy and radiation treatments would provide Blake, despite his illness, some control and autonomy while simultaneously letting Dr. Conrad accomplish his goal of getting the treatment started.

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Libby Brockman is a 2007 graduate of Brandeis University with degrees in neuroscience, biology, and psychology. She is currently involved in adolescent medicine research at the University of Washington in Seattle, and plans to attend medical school in the fall of 2009.

Megan A. Moreno, MD, MEd, MPH, is a senior fellow in adolescent medicine at the University of Washington in Seattle. After the fellowship she will be joining the pediatrics faculty at the University of Wisconsin-Madison as an assistant professor. Her research interests center on adolescents' use of technology and how it impacts their health.

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CLINICAL CASE

How Much Information Is Enough?

Commentary by Jay Jacobson, MD

Dr. Anderson glanced at the clinic schedule and saw that Mr. Taylor, a new patient, was next on his schedule. Mr. Taylor was a man in his mid-20s who had come to the clinic for treatment of a nagging respiratory virus. After finding out that Mr. Taylor had no medical home and hadn't had a check-up in the last few years, Dr. Anderson took a detailed history, during which he learned that Mr. Taylor was gay, and, while he'd had other partners in the past, had recently settled down with a man whose companionship he valued and whom he considered to be his life partner. Dr. Anderson explained that since Mr. Taylor had not seen a doctor in a while and was not feeling well, he'd like to do a physical exam and order some blood work.

When it came to ordering the blood work, Dr. Anderson asked Mr. Taylor, "When did you last have an HIV test?"

"I've never had one and neither has my partner, Dave. Both of us have always been careful in the past. Do you really think it's necessary?"

"Yes I do," Dr. Anderson replied. "Especially now that you and Dave want to make a life with each other. It will give you both the information you need. I can order the HIV test along with the other blood work we need to check out these symptoms."

"OK," Mr. Taylor agreed.

Dr. Anderson hesitated for a moment, debating his next step. How would Mr. Taylor react if he learned about the consequences of that test—specifically that Dr. Anderson would have to report an HIV-positive result to the public health department and insist that Mr. Taylor tell his partner (or risk Dave finding out from public health officials)?

Dr. Anderson worried that Mr. Taylor would not agree to the test if he had all of this information. He considered not telling Mr. Taylor, thinking he might justify this omission in the interest of safety for third parties—Dave and possibly others. Mr. Taylor might get up and leave the clinic if Dr. Anderson told him about the reporting duty, and he might not seek treatment elsewhere. If it came to that, Dr. Anderson thought, he could tell Mr. Taylor about the reporting requirement next time, when the results were in. There was, after all, a 50-50 chance he would have nothing to report.

Commentary

Dr. Anderson's hesitation and internal debate are understandable and commendable responses to the ethical conflicts presented in this case. They indicate his concern for the health of his patient, Mr. Taylor, and the safety of others, particularly Mr. Taylor's partner, Dave. In his effort to choose the most appropriate action, Dr. Anderson should consider his various obligations, how they conflict, and how to resolve or reduce those conflicts.

I can identify at least five duties that Dr. Anderson has, and some tension among them is inevitable. Dr. Anderson has a duty to diagnose his patient (in this case, Mr. Taylor), inform him of the diagnosis, recommend the best treatment, and maintain confidentiality. But he also has a duty to protect those who may be jeopardized by Mr. Taylor's actions, which may mean reporting Mr. Taylor's diagnosis to the state or by more direct notification of his partner(s).

An accurate diagnosis is the first step toward satisfying the duty to treat and recognizing whether there is a duty to warn or report. The vignette, although lacking significant details, implies that Mr. Taylor is seeking treatment for upper respiratory symptoms, complaints not unusual for patients in their mid-20s. There is nothing in the case description that suggests acute HIV infection or AIDS. Dr. Anderson must ask questions, examine Mr. Taylor, and order tests that will help explain his symptoms. If a self-limited viral infection or even a bacterial infection such as *streptococcal pharyngitis* is the probable diagnosis, Dr. Anderson may have fulfilled his obligation to diagnose. If results point to an opportunistic infection, then good medical practice requires not only its identification but also a search to identify a predisposing factor or condition. Under such circumstances, recommending or obtaining an HIV test is certainly appropriate.

The duty to diagnose, however, is not limited to investigating the chief complaint. Early, even pre-clinical, recognition of some conditions or infections, especially in persons at increased risk, affords the potential for more effective treatment for patients and possible protection from infection for others. The Centers for Disease Control and Prevention (CDC) guidelines suggest that doing risk-related or even "routine" testing for HIV is appropriate for men who acknowledge having sex with men and for competent adult patients. The CDC and the American Medical Association *Code of Medical Ethics* state that written informed consent for such testing is unnecessary [1, 2]. But in keeping with the ethical principle of respect for autonomy and the professional obligation to inform patients of what we are doing, why we are doing it, and the probable benefits and risks to them, it seems reasonable for Dr. Anderson to share at least some information about diagnostic or screening tests. What and how much information to share is not always clear.

Getting beyond Assumptions

Making assumptions about what patients think or how they will make health care decisions is rarely helpful or predictive. Assumptions abound in this case. Dr. Anderson *assumes* Mr. Taylor is concerned about reporting a positive result to the

“authorities.” If Dr. Anderson is worried that Mr. Taylor fears that the health department will disclose his positive test to Dave, he should talk to Mr. Taylor about how public health officials inform current and past patients. Many health departments have neither a policy on contact tracing nor the resources to carry it out. Those that do generally advise parties that they have been exposed to someone with an infectious disease but do not disclose the person’s name. Dr. Anderson can also tell Mr. Taylor that, if he doesn’t want Dave to learn about his HIV status from a third party, he—Mr. Taylor—can tell Dave himself.

Dr. Anderson *assumes* that the very act of reporting to the health department, regardless of its disclosure practice, will deter Mr. Taylor from consenting to testing, but he should review the evidence on this topic. A number of studies show that confidential reporting by name does not seem to deter most patients from being tested. Patients express more fear about a positive result than potential disclosure [3-5].

Dr. Anderson’s Duty to Warn

Dr. Anderson’s duty to protect others from harm applies not to a theoretical risk to unidentified others, but to serious, actual, and especially imminent threats to identified others [6]. In this case we don’t know whether Mr. Taylor is infected, or whether he poses a risk to Dave and, if so, of what magnitude. Here are some relevant factors to consider: Dave may already have an HIV infection acquired from someone else or from Mr. Taylor. He may even be the source of Mr. Taylor’s infection. In either of these situations Mr. Taylor poses no new risk to Dave. If Dave does not have HIV and Mr. Taylor does, then Dave may already have been at risk for some time, but that would depend on their sexual activities and whether they practice “safe” sex. Finally, it would be surprising if Dave were totally unaware that he was at some risk of HIV infection from his past or present sexual relationships.

Dr. Anderson should ask Mr. Taylor what concerns him most about testing and should be able to inform him about the notification procedures of the health department and the testing options in his state. He should recommend the steps that will best serve Mr. Taylor and his partner and give Mr. Taylor the relevant information he needs.

Providing Competent Care

In this case, competent care means obtaining an HIV test for Mr. Taylor. If the public health officials do not notify partners, I see no compelling reason to disclose the reporting requirement to Mr. Taylor. If the state does contact partners, and Mr. Taylor has expressed specific concerns about how and when Dave will learn about the positive test, then, in order for Mr. Taylor’s decision about testing to be an informed one, Dr. Anderson will have to disclose the reporting requirement.

If Mr. Taylor, when apprised of the reporting requirement, declines to be tested, Dr. Anderson should advise him about whether his state is one of the 48 that offer anonymous testing in addition to confidential name-reported testing [7]. If his state

does offer anonymous testing, then Mr. Taylor can learn his status, positive or negative, without disclosing his identity. If Mr. Taylor's test is positive and he chooses to be treated, Dr. Anderson would need to confirm the positive test and report Mr. Taylor's name and how to reach him to the health department. If Mr. Taylor tells Dr. Anderson that his test was positive but declines treatment, Dr. Anderson may not be obliged to report because this situation does not meet the criteria for a confirmed case. It might be prudent, however, for Dr. Anderson to ascertain his reporting requirement because some states require physicians to report likely or suspected cases. Even if he is not obliged to report in this particular situation, Dr. Anderson's concern for Mr. Taylor's partner would certainly persist [6]. Subsequent visits may provide opportunities to review Mr. Taylor's treatment decision and disclosure to and testing of his partner.

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Jay Jacobson, MD, is a professor of internal medicine and infectious diseases and chief of the Division of Medical Ethics and Humanities at LDS Hospital and the University of Utah School of Medicine. He has served on the American Medical Association's Council on Ethical and Judicial Affairs and the American College of Physicians Ethics and Human Rights Committee. In 2008 he was named a Master by the American College of Physicians.

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MEDICAL EDUCATION

Framing Permission for Halting or Continuing Life-Extending Therapies

Chris Feudtner, MD, PhD, MPH, David Munson, MD, Wynne Morrison, MD

Editor's note: Medical students are taught how to have the "breaking bad news" conversation with patients, and many students and residents gain practice in discussing end-of-life treatment goals. Physician educators at the Children's Hospital of Philadelphia have developed a framework for the very specific and difficult conversation with parents about halting life-sustaining treatment for their child, once all agree that the child is not able to survive.

When talking to parents whose children are on advanced life support, when both the clinical team and the parents understand that the child's death is imminent despite this intensive level of care, how should we frame the decision to halt or continue invasive life-extending treatments?

What Situation Are We Discussing?

Before we begin, we need to clarify precisely the scenario we are discussing by contrasting it with the scenarios that we are not. We are not talking about situations in which parents and clinicians have opposing views about the nearness or inevitability of the child's death. Nor are we discussing cases in which the clinicians feel that further life-extending treatment is "futile," but the parents disagree or have—for any reason—expressed their desire to continue life-extending treatment. In such cases marked by disagreement or conflict, the cardinal ethical task is to identify and properly manage the disagreement, and mediation or conflict management is required rather than directive counseling. Our intent is to discuss only those cases characterized by a preceding history of clear communication and strong mutual understanding between clinicians and parents, where a consensus exists regarding the goals of care. The clinician and parents, united by a shared sense of sadness that the goal of survival has receded from view, have agreed to shift the focus to the goals of promoting comfort and working to assure that the end of life is peaceful and dignified.

We also want to emphasize that the conversation we are scrutinizing here is not the one in which "bad news" is being delivered. The difficulties of delivering and receiving bad news, for the clinician and the parent, are sufficiently daunting that we strongly advise keeping the task of providing new distressing information as a separate task, complete with a distinctive set of suggestions about how to provide this information in as clear and compassionate a manner as one can. After the "bad news" conversation, following a period of time that ideally is measured in several hours or even days but may have to be as short as minutes, the conversation we are

examining moves beyond only providing information and takes on the task of making a joint decision.

Furthermore, we want to strongly advocate that clinicians caring for children who are critically ill have an initial “hopes and goals of care” conversation with parents as early as possible, ideally as soon as medical care commences. This discussion is devoted to pondering a question that the clinician can pose to the parents as: “It will help me take better care of your child if I know what you are hoping for.” Quite commonly, the parents will first express an ardent hope that the child will recover completely, or that he or she will be cured. In cases where the likelihood of recovery or cure is virtually nil, the expression of this hope does not imply that the parents are in a state of denial, but that the power and dignity of this hope, however remote, must be acknowledged. Clinicians can empathize with this hope while at the same time expanding the list of hopes: “I also wish that that hope could come true. What else are you hoping for?” Parents at this point will usually mention several other hopes (which clinicians might speak of as goals of care), including making sure that the child does not suffer, giving the child “a chance” to survive, protecting the dignity of the child, or having family members visit. This “hopes and goals of care” conversation, which must be repeated as the clinical situation changes, can provide an invaluable framework for discussing and making decisions about medical care.

What we are addressing in this essay, then, is a topic that arises after both the “hopes and goals of care” and the “bad news” discussions, when the child’s status has deteriorated to the point of imminent death; it is the topic of choosing how to frame one aspect of conversations about potentially halting or continuing invasive life-extending therapy. In what follows, we outline the desired outcomes of and principles guiding this discussion, sketch two different ways in which the decision could be framed, evaluate how these decision frames do or do not achieve our objectives, and consider how we choose among inevitable tradeoffs between these frames.

Desired Outcomes of the Conversation and How to Frame the Decision

What are the guiding principles and desired outcomes of this conversation? As always, clinicians want to be compassionate and supportive in the ways in which we interact with parents. We don’t want parents to feel pressured. We want to enable them to have a clear and sufficiently complete understanding of both the clinical situation and their values and goals of care for their child, so that their decisions on behalf of their child are well-informed and well-framed (which is the entire point of this essay). We do want them to feel, when they have made their decision, that they have acted in the best interests of their child and have exemplified what a good and loving parent would do under unimaginably sad and difficult circumstances.

How can we frame the decision of whether or not to halt life-extending therapies? Here we have two contrasting options: one in which the default action is to continue, and the other in which the default is to desist from, life-extending therapies.

How would these alternative framings be put into words? Both would start with the same preamble reviewing information about the clinical situation that should have been initially delivered in the preceding “bad news” conversation. For instance, the clinician might say to the parents of an extremely premature infant: “I know that yesterday I talked with you about the news that your child has suffered a massive stroke to his brain, and that this bad news in addition to his other medical problems made it extremely unlikely that he could survive. Today, he appears to be developing more problems from the stroke, which we know because his head is rapidly growing larger. I really wish that your son did not have any of these problems.” The clinician then should make a clear statement highlighting that the conversation is shifting to focus on a potential decision: “Given what is going on, we have a very difficult decision to make. I think we need to revisit the discussion where we talked about what we were hoping our medical care could do for your child, and decide whether it is time to stop invasive life support, which means stopping the breathing machine and removing the breathing tube, and devote all of our efforts to making sure your son is as comfortable and peaceful as possible.”

With all of what has been said thus far, the clinician has framed the decision in important and significant ways, but at this point it is the choice about the frame that we want to underscore. If the clinician believes (as outlined above) that further life-extending treatment will not be effective, but wants to maintain the customary default of continuing life support until a parent says to stop, then a clinician might say: “We can either proceed with treatment, as we are doing, or we can stop. What do you think you we should do?” and wait for the parents to answer. If, on the other hand, the clinician wants, within the confines of this particular conversation, to shift the default to halting ineffective therapies, offering a strong recommendation for stopping life-extending treatment while providing the parents with an unfettered opportunity to object, then the clinician might say words to this effect: “Based on my medical knowledge combined with what we’ve discussed and what you’ve told me, I recommend that we use medications to help your son be as comfortable as possible, stop the machine, remove the tube, and have you hold him. I know that these are difficult things to talk about, but if you accept my recommendation I would like to talk with you about when and how to do this. Can we make these plans together?”

Evaluation of Different Framing Options

What are the advantages and drawbacks of these two major options, especially in light of our primary objectives, namely to have the conversation result in a decision that is well informed, noncoerced, well framed, and will be looked back upon as proper and loving? In both, the clinical information provided to the parents is the same, so they are equally informed. What differs is how the questions are framed and whether the alternative frames are equally noncoercive and will have the same long-term implications for how the family looks back upon the decision.

The custom in medical practice has been to frame the continuation of therapy as the default action; but is this default always justified? In the context of individualized medical decision making for a specific patient, a customary default position about

starting or stopping treatment should have far less relevance than evaluation of the specific benefits and risks of treatment for that particular patient. In the case we are discussing here, that assessment of benefit and risk has concluded that halting treatment is in the child's best interest. Assessing the merits of these two frames also has to do with human psychology. In general, people view the act of explicitly stating a preferred course of action as fully subject to moral or ethical judgments, while they perceive agreeing with a recommendation as more morally accommodating and less open to ethical scrutiny or censure. Given these asymmetrical views about assertion versus agreement, our question then becomes: if parents (along with physicians) believe that halting therapy is in the child's best interest, should we frame the decision so that (1) by agreeing, the parent will be accepting the default position of continuing care (and must assert an objection in order to halt care), or so that (2) by agreeing, the parent will be accepting the default position of halting care (and must assert an objection in order to continue care)?

In clinical practice, we have collaborated with some families who have told us explicitly that they would rather not say "yes" to halting therapy, even when they firmly believe that doing so is in their child's best interest. We also have collaborated with other parents who, although less explicitly, have clearly expressed a preference for halting life-extending therapy by their quiet agreement with our proposed treatment plan. All of this occurs in the context of our society's general protreatment bias, which is a force to be reckoned with when deciding that halting treatment is the most appropriate and loving way to care for a grievously ill child. The evaluation of these options for framing the decision thus culminates in a final question: In the specific situations that we are considering here, should clinicians adhere to the common way of framing the discussion about halting life-extending therapy, due either to their deference to the status quo or to their belief that the common framing with its bias toward extending treatment is to be preferred as a general policy? Or should clinicians commit to a more individualized practice, rejecting the subtle coercion that the customary habits of framing the decision inflict upon these parents who have come to believe that halting life-extending therapy is in their child's best interest, and instead frame the discussion so that this course of action becomes the default?

Conclusion

We want in this essay to highlight the importance of how this discussion is framed and to underscore the inevitability of the tradeoffs between these two different ways of framing the decision. Neither frame for the decision—with the default option being to continue or to halt life-extending treatment, and the required action on the part of the parent being either assertion of an opinion or acceptance of a recommendation—is without dangers of resulting in a choice that does not conform to the child's best interest or that creates within the parents a feeling of being coerced. We do believe that, after having several such conversations with parents and paying assiduous attention to their stated goals and hopes of care for their child as outlined above, there is an ethically sound role for framing the default therapeutic option as halting life-extending treatment.

Suggested Readings

American Academy of Pediatrics Committee on Bioethics. Informed consent, parental permission, and assent in pediatric practice. *Pediatrics*. 1995;95(2):314-317.

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Chris Feudtner, MD, PhD, MPH, is the director of the Department of Medical Ethics, director of research, and an attending physician for PACT (Palliative Care Team) and integrated care service (ICS), all at the Children’s Hospital of Philadelphia.

David Munson, MD, is the associate medical director of the newborn/infant intensive care unit and an attending physician on the pediatric advanced care team, both at the Children’s Hospital of Philadelphia (CHOP). He directs the Fetal Palliative Care Initiative in the Fetal Diagnostic Center at CHOP and is an assistant professor of clinical pediatrics at the University of Pennsylvania. His academic and educational interests focus on end-of-life care in the intensive care unit.

Wynne Morrison, MD, is a pediatric intensivist and attending physician in palliative care at the Children’s Hospital of Philadelphia (CHOP) and The University of Pennsylvania. She is a student in the Masters in Bioethics Program at the Penn Center for Bioethics and director of the Fellowship Program in Pediatric Critical Care at CHOP. Dr. Morrison’s research interests are in physician-patient-family communication, ethics, family-centered care, and end-of-life care.

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JOURNAL DISCUSSION

How Reliable is the Competency Assessment Process?

Jorie Epstein

Appelbaum PS. Assessment of patients' competence to consent to treatment. *N Engl J Med.* 2007;357(18):1834-1840.

Within reason, it is every adult American's legal right to make his or her own decisions. Included in this right is the freedom to make decisions about one's physician, medical treatment plan, and other health care matters. A democratic society does, however, provide moral, ethical, and social guidelines within which these decisions must fall—medical and health care choices are no different. The goal of this framework is to optimize personal freedom and autonomy, while ensuring that individual choices are within the guidelines for safe, acceptable behavior and practice. The imposition of limits is a complicated matter, though, particularly when it comes to health care, where a patient must demonstrate decision-making capacity, often measured by his or her physician.

In his *New England Journal of Medicine* article, "Assessment of Patients' Competence to Consent to Treatment," Paul Appelbaum explores the criteria for determining patient competence and the tools that are commonly used for such assessment. Appelbaum recognizes that there is no tool that is "perfect" for determining competence, but offers some suggestions for maximizing the resources physicians have.

Physicians are required, according to law and medical ethics, to obtain a patient's informed consent before the patient undergoes any nonemergency procedures or receives any treatment [1, 2]. While physicians may attempt to gauge a patient's ability to make treatment-related decisions through regular communication during the clinical encounter [3], they often rely on the "experts" (e.g., psychiatrists) to determine competence. Requests for inpatient psychiatric assessment of competency account for 3-25 percent of all requests for psychiatric consultations [4]. These requests demonstrate the physicians' awareness of the importance of accurately judging patient capacity. Still, nonpsychiatrist physicians overwhelmingly determine patient fitness to make treatment decisions on their own.

Appelbaum reviews two well-known tools for establishing patient competency, the Mini Mental State Exam (MMSE) and the MacArthur Competence Tool for Treatment ("the MacArthur tool") [5]. Each method seeks to assess a patient's ability to: communicate a choice, understand relevant information, appreciate the

consequences of treatment versus nontreatment, and reason about treatment choices [3]. The MMSE “has been found to correlate with clinical judgments of incapacity and it may have some use in identifying patients at the high and low ends of the range of capacity” [5]. The MacArthur tool (Appelbaum discloses he helped develop the tool and receives fees from the sales of the manual, forms, and training tapes), “incorporates information specific to a given patient’s decision-making situation” [5]. Both tests, however, ultimately rely on the subjective judgments of the physician, and, Appelbaum admits, there is a professional “divergence of opinion about which criteria should be applied and how” [6].

Regardless of the assessment method, Appelbaum believes that “examiners should first ensure that patients have been given the information that is relevant to making an informed decision about their treatment” [5]. He says that disclosure should include information about the patient’s condition, nature of the proposed therapy, the risks and benefits, and alternative treatments [5]. For patients who are receiving mind-altering medications or those experiencing fluctuations in mentation, more than one evaluation may be necessary [7].

Overall, Appelbaum’s recommendations tend to favor finding the patient competent. In his model, physicians are encouraged to “make treatment decisions...[that] reflect a societal judgment about the appropriate balance between respecting the patient’s autonomy and protecting the patient from the consequences of a bad decision” [8]. He offers strategies to alleviate patients’ fears and anxieties and, when possible, suggests evaluating a patient several times before labeling him or her incompetent [6]. Appelbaum believes that the stringency of the test should vary with the seriousness of the likely risks and benefits of patients’ decisions [8]. In practice, this means holding patients who are facing more serious procedures and therapies to higher standards of competence. Recognizing that some may find fault with this “sliding scale” approach, Appelbaum defends it by pointing out that it has been endorsed by the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and the courts [9]. Still, it is reasonable to ask that physicians take the positive endorsement and the criticisms of this “sliding scale” into account before applying it into clinical practice.

Critiquing Appelbaum’s Approach

While Appelbaum’s approach to assessing competency using the MMSE and the MacArthur tool and using a generous threshold for competency may be reasonable on balance, I can see several problems with his model. First, by what standards is the physician basing his or her judgment of the patient’s understanding? Furthermore, reliance on the standardized tools assumes that the physician has taken the time to explain the patient’s condition adequately and answer his or her questions—something that perhaps should not be assumed. In short, I believe that the overarching question is: how reliable are these assessments?

My first point concerns the standards that physicians use to draw a conclusion regarding competence. While physicians who base their judgments on current legal

standards or on standardized question sets increase their interrater reliability [5], are they in agreement about what constitutes patient decision-making capability? Appelbaum admits that the MMSE is quite helpful for confirming that patients are almost surely competent (those with a score of 23 or higher on the 30 point scale) or that are almost surely incompetent (those scoring 19 or lower), but there is a three-point “gray area” that is completely reliant on physician judgment [5]. As Appelbaum notes, “no single cutoff score yields both high sensitivity and high specificity” [5]. The MacArthur tool also has a serious shortcoming: “evaluators must integrate the results with other data in order to reach a judgment about competence” [5]. Exactly what “other data” should be collected and included in the assessment is not specified. Appelbaum indicates that administration of the test can be laborious, too, if one is unfamiliar with the tool [5].

One can see that the tests, while potentially helpful, are plagued by limitations, not the least of which is how to administer them more consistently. In order to achieve greater uniformity, a physician must know how to execute the exams properly. But do physicians receive specialized training for the specific assessment they will give? If the test itself is standardized, what are the procedures for administering it? Appelbaum states that “there are currently no formal practice guidelines from professional societies for the assessment of a patient’s capacity to consent to treatment” [6], forcing one to ask, how useful are these assessment tools?

The Informed Consent Process

My second point has to do with informed consent process. Appelbaum gives this little attention in the article, speaking about it specifically only when discussing situations in which an outside evaluator is called upon. He writes:

Whatever approach to assessment is used, examiners should first ensure that patients have been given the information that is relevant to making an informed decision about their treatment...such disclosure cannot be presumed...the evaluator should ask a physician responsible for the patient’s care to disclose the relevant information again in the evaluator’s presence or the evaluator should undertake such disclosure [7].

Appelbaum’s willingness to gloss over this very important process is quite problematic. Before patients can be properly evaluated for competency, they must be given information related to their condition. If physicians fail to do their “due diligence” in this area of patient-physician communication, patient decisions will be based on incomplete, and perhaps incorrect, information, which can lead to unwarranted questions or negative assumptions about the patient’s competence. Further, physicians must do more than just tell patients about a proposed procedure or therapy and its risks and benefits. They must communicate in ways that patients understand, even if it means requesting a language translator or using terms that are understandable to those who are not trained in medicine. Physicians must also ask questions that compel the patient to demonstrate a deeper understanding of the treatment proposals, not merely prompt the patient to parrot information back.

Another consideration that doctors must factor into their competency determination is how a patient's financial situation impacts the decision-making process. According to the American Medical Association's "Voice for the Uninsured" campaign, 1 in 7 Americans is without health insurance [10]. I think that it is entirely possible that, for some patients the decision about an elective procedure may be more difficult to make than the decision about whether to undergo treatment for a life-threatening condition. When a patient is uninsured or underinsured, he or she is likely to have more than just the risks and benefits to consider. The patient might also weigh which procedure is least expensive, which will be best covered by his or her insurance, or which has the quickest recovery time so that he or she can return to work. Because interventions for life-saving illnesses are more likely to be subsidized by insurance, patients may be willing to undergo those procedures more readily than they would less serious or preventive procedures that, while important, are not covered by insurance. The combination of necessity and health insurance can thus significantly simplify or complicate the patient's decision-making process. Physicians must carefully judge whether a patient's decision—especially if it is suboptimal in the doctor's opinion—is one of incompetence and negligence or of pragmatism and personal choice.

Conclusion

Appelbaum has provided a good overview of the tools used for assessing patient competence. This article assumes that the physician has communicated effectively with the patient about the latter's diagnosis, treatment options, and the risks and benefits of those options—including the option of no treatment at all. Assuming that the informed consent process was managed effectively, as this article does, leaves a big piece of the competency assessment puzzle missing. Readers will have to make use of Appelbaum's many bibliographic references to complete the picture.

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Jorie Epstein completed her undergraduate degree at the University of Chicago in 2008 and is a research assistant in ethics at the American Medical Association in Chicago. she will begin a master's program in social work at the University of Chicago School of Social Service Administration in the fall of 2008.

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CLINICAL PEARL

The Hazards of Stopping a Brain in Motion: Evaluation and Classification of Traumatic Brain Injury

Kristin M. Johnson, DO

Traumatic brain injury (TBI) is one of the leading causes of morbidity and mortality in young people in the U.S. [1]. It is estimated that TBI occurs in 1.5 million people each year. About 1.1 million are seen in emergency departments or clinics and then released; around 400,000 people with mild or moderate TBI are never seen by medical personnel; and another 235,000 must be hospitalized [2, 3]. Of the hospitalized, 50,000 die and 80,000 are left with permanent sequelae [2]. Falls account for about 28 percent of all TBI, followed by motor vehicle collisions at 20 percent and motor vehicle-pedestrian accidents at 19 percent. Assaults account for only 11 percent of TBI overall [4], although moderate and severe TBI in a child under the age of 4 is often secondary to child abuse. The risk of TBI is almost twice as great in males as in females. Those at greatest risk, however, are adolescents and young adults, aged 15 to 24 years, and children under age 4.

Traumatic brain injury has been defined in a variety of ways and is often used interchangeably with the term head injury. Both phrases refer to injuries caused by external forces to the head that lead to temporary or permanent impairments in brain function. Mechanisms for injury can be contact or inertial. Contact injuries occur when impact is delivered to the head at rest and results in skull fractures, epidural or subdural hematomas, and contusions, i.e., focal injuries. Inertial injuries occur when the head is set into translational or rotational motion, with or without a contact force, leading to a more diffuse injury. In both circumstances, injury occurs when these forces cause greater strain than the brain structure can tolerate. Brain injury can be subdivided into primary injury, which occurs immediately, and secondary injury, which begins right after the primary injury and may continue for an unpredictable length of time.

Primary Brain Injury

Primary injuries include skull fractures in the vault or basilar region, intracranial hematomas, contusions, and diffuse brain injury. Skull fractures are associated with hematomas, cranial nerve damage, and worsening of brain injury.

Subdural hematomas are most common, seen in 20-25 percent of all patients who become comatose following brain injury [5]. This type of hematoma is caused by the tearing of bridging veins over the cortex or the venous sinuses and is associated with a mortality rate of 40-60 percent in patients who require surgery [6]. Subdural

hematomas are also regarded as one of the most characteristic central nervous system lesions encountered in shaken baby syndrome.

Epidural hematomas occur between the skull and the dura, typically after laceration of the middle meningeal artery. These are not as common as subdural hematomas and are usually seen in only 8-10 percent of comatose patients [7].

Duret hemorrhages, or hemorrhage in the pons or midbrain, usually occur as a result of herniation and typically result in death or a persistent vegetative state.

Contusions are punctuate (or capillary) hemorrhages, edema, and necrosis that originate in discrete regions and then coalesce with age to look more like intracerebral hematomas. Found in 20-25 percent of patients with severe TBI, contusions occur most often in the anterior temporal lobes and inferior frontal cortex due to shifting of the brain over the irregularly shaped skull in these regions [7]. Contusions are classified as either coup (injury to brain tissue under the point of impact) or contrecoup (injury to the brain opposite the site of impact occurring when the brain is in motion). Laceration or punctuate contusion at the gray-white junction, within the corpus collosum or brainstem is seen with diffuse axonal injury (DAI). Almost half of severe TBI patients and one-third of those who die have diffuse axonal injury. There is evidence that DAI may not be a primary injury, but may in fact fall into the secondary injury category [8].

Secondary Brain Injury

Within minutes of head trauma, cascades of destructive neurochemical, neuroanatomic, and pathologic processes begin, resulting in more severe brain injury. Circulation of excitatory amino acids including glutamate and aspartate increases significantly, leading to swelling and neuronal death. Elevated levels of extracellular potassium can cause cerebral edema and increased cytokines, producing more inflammation. As intracranial pressure increases, so does the severity of TBI. If the pressure exceeds 40 mmHg, cerebral hypoxia, ischemia, edema, hydrocephalus, and herniation can occur. Hypotension and hypoxia have been associated with greater morbidity and mortality; in fact, hypotension nearly doubles the mortality from TBI. It is these secondary injuries that predict the final outcome for the patient. Intracranial pressure from the processes just described, for example, causes compression of the brain that can produce supratentorial or cerebellar herniations.

Evaluation of Patients with TBI

Upon evaluation, patients with traumatic brain injury are placed in one of three categories; minor, moderate, or severe head trauma. This initial evaluation includes securing a patent airway and restoring normal respirations. Fluid resuscitation to maintain the systolic blood pressure above 90 mmHg is imperative to prevent hypotension that results in decreased cerebral perfusion, worsening cerebral ischemia, and increased mortality. All TBI patients should be treated as though they have a spinal fracture until it is determined that they do not. Patient status is assessed using the Glasgow coma scale (GCS). Scores from the GCS's three component

scales—speech (1-5), eye opening (1-4), and motor response (1-6)—are added together to provide a final score.

Minor TBI

Patients with minor head trauma have an isolated head injury and a GCS score of 14 to 15 [9]. Most patients with minor head trauma are asymptomatic when they arrive at the ED or urgent care facility. If symptoms are present, they are typically headache (most common), nausea, vomiting, disorientation, confusion, or amnesia. Although most of these patients generally do very well, 3 percent have sudden neurological deterioration [10]. Unfortunately, there is no good way to tell who will fall into this very small group of patients—some say any history of loss of consciousness is an indicator, others say it is the length of the loss of consciousness [9, 11].

The need for imaging in this group is also debated [11]. Is it helpful to image the patients, or is keeping them in the hospital overnight and watching them closely for signs of changes in their neurologic examination just as safe and effective? Neuroimaging is generally not indicated in sober, low-risk patients. Low-risk patients are those who are asymptomatic, uninjured, have a normal exam, and have a trivial mechanism of injury. Those with moderate risk—with initial GCS of 15, normal exam, brief loss of consciousness, vomiting, headache, and intoxication—should have a CT of the head or prolonged stay in the hospital for monitoring. High-risk patients have focal neurologic findings, asymmetric pupils, multiple traumas, initial GCS of 14 to 15, loss of consciousness, headache, nausea, vomiting, seizure, intoxication, and much more [12]. These patients should undergo CT scanning and inpatient monitoring. Most low-risk patients with minor head trauma can be safely discharged after the initial evaluation to be monitored by someone at home over a 4-6 hour period. If there are any concerns, or no one at home to monitor the patient, he or she should be kept for observation.

Moderate TBI

Patients with moderate TBI have a GCS score of 9 to 13 and a variety of symptoms. They often describe brief posttraumatic seizures, loss of consciousness, and confusion. The most challenging patient in this category is the one who arrives lucid and then rapidly declines. Around 75 percent of these patients have either subdural or epidural hematomas [13]. If caught early, they do well, but those with an initial GCS greater than 9 who deteriorate to less than 8 have worse outcomes than those with severe TBI (GCS less than 8) [14]. Diligence is the key to achieving the best outcome with these patients. They require close clinical observation, serial CT scans with changes in exam, and early neurosurgical intervention. If a neurosurgeon is not readily available, immediate intervention with hyperventilation and osmotic therapy should be initiated.

Severe TBI

Patients with a GCS less than 8, and any intracranial contusion, hematoma, or brain laceration have severe TBI. Prognosis is determined by pupillary response, age,

medical conditions, motor exam on arrival, and other injuries [15]. Around one-fourth of patients with severe TBI eventually require neurosurgical intervention for intracranial lesions [16]. Adult patients who survive severe traumatic brain injury (mortality is approximately 60 percent), are inevitably left with severe disability [17]. In children, the mortality is much lower, as is the likelihood of significant, permanent disability [18].

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Kristin M. Johnson, DO, is a neurologist at Riverside Methodist Hospital in Columbus, Ohio, where she supervises medical students, interns, and residents. She has a special interest in neuromuscular medicine and neurocritical care.

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HEALTH LAW

The Legal Boundaries of Informed Consent

Olubukunola Mary Tawose

Kimberly Randall was born on January 19, 1987. A seemingly healthy baby girl, she would later be diagnosed with juvenile laryngeal papillomatosis (JLP), a disease that causes warty growths from the nose to the lungs in the respiratory tracts of children and has an estimated mortality rate of 5 percent. The disease is managed by removing the warts from the throat using laser surgery, but they regrow immediately after removal. Throughout her pregnancy, Kimberly's mother complained of vaginal discomfort and of seeing tissue coming from her vaginal area. It would later be found that Kimberly had contracted JLP from her mother while in the birth canal because Ms. Randall was infected with the human papilloma virus (HPV). Ms. Randall's physicians were aware of the HPV, the risks associated with vaginal birth, and treatment for pregnant women with genital HPV, but they failed to warn her of the risks [1].

Ms. Randall sued Walter Reed Army Hospital for malpractice. The resulting case, *Randall v. United States*, explored how much patients must be told of their medical condition and treatment options and the extent of physicians' responsibility to inform their patients of the risks of medical procedures. Physicians have medical training, experience, and knowledge of their patients' medical history and current condition to draw upon when considering the risks and benefits of medical procedures, but they cannot know with precision how their patients will weigh that information. It is because of this uncertainty that the law requires physicians to fully inform patients of the risks associated with the medical procedures being considered so that patients can weigh the risks in light of their own values and goals.

The Legal Matter of Informed Consent

Informed consent, a relatively new concept to the legal profession, first arose in the context of assault and battery in civil tort procedures. The law recognizes an individual's right to have "complete immunity of his person from physical interference of others... . Any unlawful or unauthorized touching of the person of another...constitutes assault and battery" [2]. In other words, a patient's consent must be given, either expressly or implicitly, before a physician may legally "interfere" with the physical body of the patient. Hence, in past tort cases, physicians have been found guilty of assault and battery because they did not allow their patients to be the final decision makers about undergoing a medical procedure. Consent is also needed because the physician and the patient are entering into a contract in which the physician will employ skills and judgment to bring about desired results and, in

return, receive payment from the patient. Contracts demand consent of all parties, making a patient's knowledge of what he or she is consenting to essential [3].

Informed consent became a vital part of patients' rights in the 1970s, as illustrated in the landmark case of *Canterbury v. Spence* [4]. The court held in that case that "the patient's right of self-decision shapes the boundaries of the [physician's] duty to reveal" [5]. The court found that a patient must be fully informed by the physician or other health care provider so that he or she can make an intelligent choice as to which medical procedure, if any, to undergo. Physicians must communicate to their patients information that is "material" to the decision at hand, including all risks associated with the procedure that might sway the patient's decision. A risk is "material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy" [6]. In other words, if a physician fails to inform a patient of risks that he or she knows are important or that may have an impact on the patient's decision about the proposed therapy, then the physician is legally liable for not fully informing the patient.

There are two exceptions to this rule. The first exception comes into play when the patient is unconscious or otherwise incapable of consenting, and the possible harm from a failure to treat outweighs the harm from the proposed treatment [7]. The second exception, known as the therapeutic privilege principle, acknowledges that in some situations the disclosure of certain risks would not be in the patient's best medical interest. This principle must be exercised with great care and discretion and should not be used as an excuse to withhold bad news. It applies only when, in the physician's clinical judgment, disclosure would exacerbate the patient's condition [8].

The Case of Jacqueline Randall

Jacqueline Randall charged that her physicians' failure to inform her of the risks to her infant from a vaginal birth resulted in the medical need for 25 procedures over 7 years to treat her daughter's JLP. Her physicians were aware that she had irregular cells in her Pap smear before becoming pregnant and, Randall claimed, she should have been counseled to consider a caesarean section to eliminate the risk of JLP; a reasonable person, the case alleged, would have wanted this information.

The court found that the physicians at Walter Reed Army Hospital knew or should have known that Jacqueline Randall had HPV at the time of her daughter's birth. Her doctors conceded that there was an obligation to inform Ms. Randall of the risks associated with each mode of delivery and to provide her with options. The court further found that, despite the fact that there was no standard method of treatment or a procedure to counsel a patient with HPV, the physicians had an obligation to tell Ms. Randall of the risks associated with HPV and a vaginal delivery. Lastly the court decided that a reasonable, prudent person in Ms. Randall's position, having been made aware of the risks and severity of JLP in an infant, would have chosen to have a caesarean section [9].

A Path to Follow

By not informing her of the risks of having a vaginal delivery while suffering from HPV, Jacqueline Randall's physicians eliminated her ability to choose delivery by caesarean section. Physicians can avoid the repercussions that the Walter Reed physicians faced by communicating risks that their patients would find "material." The *Canterbury* court had concluded that not all information related to the proposed medical procedure must be disclosed, only the information that a reasonable person would find necessary when making an informed decision [10]. If physicians cannot discern what information is important, then disclosing all possible risks about the procedure would be prudent. Keeping patients informed has become legally and ethically imperative because patients base their decisions about whether to risk their lives or those of loved ones on what they are told by their physicians.

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Olubukunola Mary Tawose is a second-year law student at Saint Louis University School of Law, where her focus is on health and international law. She is currently working on a study entitled "Teaching Professionalism" at the University of Chicago. She graduated with an AB in the history, philosophy, and social studies of science and medicine from the University of Chicago in 2007. As an attorney, she will pursue a career in the field of medical ethics policy.

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POLICY FORUM

Role of Independent Advocates for Research Subjects Who Are Child Wards of the State

Hafzah Mueenuddin, JD, and Eric D. Kodish, MD

Research with children presents a formidable “boundary case” for informed consent, demarcating an ethical limit to the consent doctrine. We have even gone so far as to question the very existence of informed consent for pediatric research, suggesting that parental permission is a fundamentally distinct ethical concept [1]. More stringent protection from research risk is provided for children because they are recognized as a vulnerable category of human research subjects. Children without parents (wards of the state) are likely to be even more vulnerable. Widely publicized and ethically controversial research involving this population of vulnerable subjects, such as the hepatitis studies at the Willowbrook State School for “mentally defective persons” from 1956 until 1972 and anti-retroviral trials that used foster children in New York City as research subjects in the more recent past, point to the need for clear and consistent policy in this domain.

The Code of Federal Regulations, Part 46, subpart D describes four categories of research with children that may be approved by institutional review boards (oversight boards charged with maintaining ethical standards in research institutions). They are:

- research not involving greater than minimal risk (category 46.404);
- research involving greater than minimum risk but presenting the prospect of direct benefit to individual subjects (category 46.405);
- research involving greater than minimal risk and no direct benefit to individual subjects (category 46.406);
- research not otherwise approvable which represents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (category 46.407) [1, 2].

The regulations provide highly specific guidance with regard to wards of the state who are candidates for categories 406 and 407 research, but are curiously silent about minimal risk research (category 404) and higher risk research with the prospect of direct benefit to the child (category 405). Having consistent guidelines across all four categories is desirable to prevent the exploitation of children who are wards of the state while at the same time allowing ethically sound research to move forward. Research on wards of the state that does not exceed the “minimal risk” threshold is not likely to be controversial, so in this article we focus on research with

wards of the state that may expose children to greater than minimal risk while at the same time presenting the prospect of direct benefit to the child (category 405).

Greater than Minimal Risk

In the research category of greater than minimal risk, including more than a minor increase in risk, where there is a prospect of direct benefit, the judgment of investigators, institutional review boards, and parents is typically considered sufficient to protect children from unnecessary risk. Wards of the state often do not have parents who are capable of or available to assess the risk and benefit of research for their children. Writing recently in the *Journal of Pediatrics*, Sumeeta Varma and David Wendler recommend that, when parents are unable or unavailable to protect their child's interest, independent advocates should be asked to protect the ward's interest [3]. Such advocates are currently mandated for research categories involving greater than minimal risk with no likely benefit for subjects—406 and 407.

Ideally, advocates should understand the proposed study and be able to place its risks and benefits in the context of the individual child's needs. It is important to determine the probability and magnitude of both the risks and the benefits of a study when assessing whether the child's needs are being served by participation. For example, if an investigational drug had a 40 percent likelihood of curing an otherwise fatal pediatric cancer, the benefit would outweigh a 5 percent risk of fatal toxicity. While the probability of the benefit is somewhat low, the magnitude of saving a child's life is great, and the risk of fatal toxicity is, on balance, acceptable. If a different investigational drug had a 90 percent likelihood of increasing a child's IQ by 10 points but carried the same 5 percent risk of fatal toxicity to the child, few would argue that the potential benefit outweighed the potential harm. Here, while the probability of benefit is very high, the magnitude of the benefit to the child does not outweigh the risk. An increase of 10 IQ points is not likely to change a child's quality of life significantly or be worth taking the chance that the child would suffer fatal toxicity. These examples illustrate the need to weigh benefit against risk for any child, but may be especially helpful for individuals who have been legally appointed to serve *in parens patriae* for wards of the state.

Both parents and advocates are expected to complete this risk/benefit analysis prior to enrolling a child in research. While it is reasonable to assume that all parents want to protect their children from excessive risk, this is not always the case. For wards of the state, it is quite possible that they came under government custody precisely because their parents were unable to fulfill this obligation. Varma and Wendler point out that advocates appointed for wards participating in categories 406 and 407 studies are often assigned several cases to oversee [4]. In category 405 studies, where risk and prospect of direct benefit must be balanced for each child, optimal policy would limit the number of children assigned to any single advocate, allowing the advocate to devote sufficient time and consideration to the potential participation of each child in the research.

In sum, advocates should be assigned to provide permission before wards of the state can participate in category 405 research, i.e., research with greater than minimal risk but with the possibility for direct benefit for the individual subject. The advocate should be well versed in the potential risks and benefits of the proposed study and in how the intervention is likely to affect the individual child. The number of cases assigned to advocates should be limited to ensure that a thorough assessment can be made of how risks and benefits will affect each child's needs. This will allow for more consistent regulation and assure appropriate balancing for "boundary cases" such as wards of the state who are candidates for pediatric research.

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Hafzah Mueenuddin, JD, is a fellow in the Cleveland Fellowship for Advanced Bioethics at the Cleveland Clinic. She graduated from Cleveland-Marshall College of Law in 2007, and her interests include end-of-life decision making and reproductive ethics.

Eric D. Kodish, MD, is the F.J. O'Neill Professor and chairman of the Department of Bioethics at the Cleveland Clinic. He is professor of pediatrics at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University. He is also the editor of *Ethics and Research with Children: A Case Based Approach* published by Oxford University Press (2005).

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The Patient's Piece of the Informed Consent Pie

Abraham P. Schwab, PhD

I've tried to quit smoking more times than I can count. Several years ago, I asked my family physician for a well-known drug to help me quit. He responded by providing me with a list of support groups, suggesting I try one. I responded that I was not a "support group" person. He suggested I try one anyway. The interaction struck me as odd, given that the physician and I clearly had the same goal—I was to quit smoking—but the physician was dictating the means of achieving that goal.

Part of my surprise in this case arose from my confusion about the role of informed consent in medical practice. In what follows I provide a more accurate, though less appealing, view of informed consent. The concept of informed consent has been defined in many ways: shared decision-making [1], an attempt to balance patient self-determination and patient well-being [2], a necessary supplement to physician altruism [3], and a ritual of trust [4]. Despite all these definitions, this practice, this legal requirement, this form we must sign before receiving care, is not particularly well understood by medical practitioners and patients.

Take for example a recent piece in the *Journal of General Internal Medicine* by Peter Schwartz and Eric Meslin [5]. In the abstract they note a relationship between, "the ethical principle of *respect for autonomy* and its application in informed consent *or* [emphasis added] shared decision-making." Early in the article they state: "This principle [of respecting patient autonomy] requires, among other things, that patients guide their health care by providing informed consent to proposed interventions *or* [emphasis added] by participating in shared decision making" [5]. They conclude with, "while *respect for autonomy* is central to health care ethics, it can be difficult to clarify what level of disclosure or understanding is necessary for a specific patient in a specific situation. . . to adequately consent to medical interventions" [6]. While accurately indicating that there exists some relationship between respect for autonomy, informed consent, and shared decision making, these quotes fail to recognize the very limited scope of informed consent and the substantial differences between its requirements and those of shared decision making. Specifically, as every physician knows, informed consent is legally required. As an aspect of patients' autonomous decision making, however, informed consent is a negative—not a positive—expression of autonomy. Shared decision making, on the other hand, is more likely to include positive expressions of patient autonomy, but it is not legally required and may or may not be part of the patient-physician encounter.

Schwartz and Meslin follow a view common to the discussion of informed consent in bioethics. Buchanan and Brock's [2] well-known discussion of competence is representative of this "patient-centric" view. On their view, two values ground the practice of informed consent: promoting the *patient's* well-being while preserving the *patient's* self-determination. Yet the legal, clinical, and etymological background of informed consent suggest otherwise. The legal history emphasizes the right of refusal—patients must be informed so that they can agree (or not) to what the physician recommends [7]. The clinical history of informed consent emphasizes an ever-increasing encroachment on physician authority—interventions previously performed without patient consent now require it (e.g., childhood immunizations), though this is not true in all cases (e.g., episiotomy). The language itself, "informed" and "consent," implies that physicians make a judgment to which patients agree (or not). In short, informed consent is less about patient decisions than it is about restraining physicians. Informed consent operates like a pie crust that keeps the filling of physician judgment and activity from spilling onto the table and the floor—it constrains physician activity; it does not enhance patient autonomy.

In the best cases, then, to push the pie analogy a little further, patients are allowed in the kitchen but they are not allowed to touch the ingredients or use any utensils to help with the pie filling. When asked, the patient may choose among fillings the physician offers, but they are not entitled to produce their own filling or direct what fillings the physician offers. The patient may also refuse every filling the physician offers, and so refuse to make a pie.

Competence, power relations, and bias further attenuate the meaningfulness of a right of refusal. First, patients may lack even the basic components of decision-making competence; they cannot meaningfully say "no." Second, information can be challenged by the patient (e.g., "Why do you recommend that?"), but the physician is the locus of control for the structure of the process and the type and amount of information provided. Third, the biases of human judgment often undermine patient decision making so that the decision to say "no" reveals more about the conditions under which the decision was made than about the preferences of the patient.

Setting aside the important, though well-covered, questions about competence, the effects of power and the implications of bias warrant a few more words. Patients and physicians inhabit different positions of power—physicians with esoteric knowledge of potential benefit and patients with the right of refusal. These differences in power structure the informed consent process in unappealing ways. Specifically, physicians are the means through which patients' refusals become possible. That is, physicians make patients aware of those interventions that they (the patients) are empowered to refuse—patients' ability to restrain physician activity is the responsibility of the physicians themselves. Ready-made consent forms ease the discharge of this responsibility. Much like a ready-made pie crust, consent forms have been standardized to limit the need of physicians to be actively involved in reining in their work, the refusal of their recommendations. Far from ideal, the ready-made pie crust still controls the filling better than no crust at all.

The problems of a ready-made pie crust and other means of limiting physician involvement in informed consent (e.g., having the nurse do it) are even less appealing when the biases of patient judgment are considered. Large numbers of studies illustrate the predictable biases in human judgment, many using hypothetical or actual medical judgments [8-12]. What this research means for informed consent is not entirely clear, but a few preliminary conclusions can be drawn. First, certain conditions give rise to biased decisions to consent (or refuse) by patients. Second, these conditions can be controlled by medical practitioners. Take for example the effect of presenting information as proportions rather than as percentages. Robust evidence indicates that information presented as proportions leads to more accurate interpretations of the information by both lay individuals and experts [13]. Naive and expert decision makers alike have been shown to identify more accurately the implications of this statement: “The test accurately identifies 8 out of 10 true positives and 9 out of 10 true negatives for a disease with 1 out of 100 prevalence”; than of this statement: “The test identifies 80 percent of true positives and 90 percent of true negatives for a test with 1 percent prevalence.” The decision to present in one manner rather than the other, however, rests solely with the clinician. The physician who views the principle of informed consent as a means for allowing naive patients to determine the adequacy of his or her clinical recommendations lacks motivation to incorporate these conclusions from cognitive psychology.

In sum, informed consent is the patient’s only piece of the pie that is medical care. This piece is best represented as the crust—the limit on the filling that is physician activity. This crust, however, is often provided to the patient by less-than-ideally motivated physicians or other medical practitioners in the manner that they, and not the patient or other experts (i.e., cognitive psychologists), deem appropriate.

Going back to my attempt to quit smoking, I had no legal right to demand pharmaceutical assistance. My only choice was consenting to go to the support group or refusing it. I did not go.

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Abraham P. Schwab, PhD, is an assistant professor in the Philosophy Department of Brooklyn College of the City University of New York. He works in the “no man’s land where epistemology, moral philosophy, and the study of medical practice meet.” His areas of interest include research ethics, clinical decision making (patient and physician), and naturalized moral epistemology.

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AUGUST 2008 CONTRIBUTORS

Libby Brockman is a 2007 graduate of Brandeis University with degrees in neuroscience, biology, and psychology. She is currently involved in adolescent medicine research at the University of Washington in Seattle, and plans to attend medical school in the fall of 2009.

Erin A. Egan, MD, JD, is an assistant professor of medicine at the University of Colorado Denver, a faculty associate with the Center for Bioethics at the University of Colorado Denver (UCD), and a visiting lecturer at the Neiswanger Institute for Bioethics and Health Policy at the Loyola University Stritch School of Medicine in Maywood, Illinois. She serves on the ethics consultation subcommittee, the ethics committee, and the organizational ethics committee at UCD, is the director of quality improvement for the Hospital Medicine Group, and the program director for the Holocaust in Contemporary Bioethics Program.

Jorie Epstein completed her undergraduate degree at the University of Chicago in 2008 and is a research assistant in ethics at the American Medical Association in Chicago.

Chris Feudtner, MD, PhD, MPH, is the director of the Department of Medical Ethics, director of research, and an attending physician for PACT (Palliative Care Team) and integrated care service (ICS), all at the Children's Hospital of Philadelphia.

Jay Jacobson, MD, is a professor of internal medicine and infectious diseases and chief of the Division of Medical Ethics and Humanities at LDS Hospital and the University of Utah School of Medicine. He has served on the American Medical Association's Council on Ethical and Judicial Affairs and the American College of Physicians Ethics and Human Rights Committee. In 2008 he was named a Master by the American College of Physicians.

Kristin M. Johnson, DO, is a neurologist at Riverside Methodist Hospital in Columbus, Ohio, where she supervises medical students, interns, and residents. She has a special interest in neuromuscular medicine and neurocritical care.

Eric D. Kodish, MD, is the F.J. O'Neill Professor and chairman of the Department of Bioethics at the Cleveland Clinic. He is professor of pediatrics at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University. He is also

editor of *Ethics and Research with Children: A Case Based Approach* published by Oxford University Press (2005).

Megan A. Moreno, MD, MEd, MPH, is a senior fellow in adolescent medicine at the University of Washington in Seattle. After the fellowship she will be joining the pediatrics faculty at the University of Wisconsin-Madison as an assistant professor. Her research interests center on adolescents' use of technology and how it impacts their health.

Wynne Morrison, MD, is a pediatric intensivist and attending physician in palliative care at the Children's Hospital of Philadelphia (CHOP) and the University of Pennsylvania. She is a student in the Masters in Bioethics Program at the Penn Center for Bioethics and director of the Fellowship Program in Pediatric Critical Care at CHOP. Dr. Morrison's research interests are in physician-patient-family communication, ethics, family-centered care, and end-of-life care.

Hafzah Mueenuddin, JD, is a fellow in the Cleveland Fellowship for Advanced Bioethics at the Cleveland Clinic. She graduated from Cleveland-Marshall College of Law in 2007, and her interests include end-of-life decision making and reproductive ethics.

David Munson, MD, is the associate medical director of the newborn/infant intensive care unit and an attending physician on the pediatric advanced care team, both at the Children's Hospital of Philadelphia (CHOP). He directs the Fetal Palliative Care Initiative in the Fetal Diagnostic Center at CHOP and is an assistant professor of clinical pediatrics at the University of Pennsylvania. His academic and educational interests focus on end-of-life care in the intensive care unit.

Abraham P. Schwab, PhD, is an assistant professor in the Philosophy Department of Brooklyn College of the City University of New York. He works in the "no man's land where epistemology, moral philosophy, and the study of medical practice meet." His areas of interest include research ethics, clinical decision making (patient and physician), and naturalized moral epistemology.

Olubukunola Mary Tawose is a second-year law student at Saint Louis University School of Law, where her focus is on health and international law. She is currently working on a study entitled "Teaching Professionalism" at the University of Chicago. She graduated with an AB in the history, philosophy, and social studies of science and medicine from the University of Chicago in 2007. As an attorney, she will pursue a career in the field of medical ethics policy.

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