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The Ethics of Shared Decision Making

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FROM THE EDITOR
Transforming the Patient-Physician Relationship: The Future of Shared Decision Making

Since the 1970s, the credo of progressive medical practice has been shared decision making, which rejects the "doctor knows best" approaches to care, prioritizing the preferences and goals of patients. Slowly, medical schools have adapted curricula to emphasize bedside manner and cultural competency, and many practices have shifted to a medical-home model that takes patient-centered, a team-based approach to care.

While there is no question that patients have benefitted from many such innovations, it is also clear that realizing truly shared decision making would require altering current medical practice profoundly. For example, research on decision making at the end of life has shown that far more people wish to die at home than actually do. It takes little imagination to foresee the degree of change in culture and structure of medicine that would be needed to guarantee that the majority of people died in a setting and manner of their choosing. This issue of *Virtual Mentor* shows that improving shared decision making in a meaningful way will significantly change medical culture and systems for the better, from ideas about consent and autonomy to medical education to health care policy.

First, Jane DeLima Thomas, MD, discusses a common dilemma in shared decision making: that of the patient who seems to harbor unrealistic expectations. Dr. Thomas recognizes that communication and information are, in a sense, interventions like any other and should assessed in terms of their risks of harm as well as promises of benefit.

Several articles explore informed consent. This month's excerpt from the AMA *Code of Medical Ethics* includes the opinions on informed consent and withholding information from patients. Bryan Murray's contribution to the health law section reviews the legal history and definitions of informed consent. In an op-ed, Zain Mithani, MD, considers whether physicians should seek patients' consent before prescribing medications for off-label use and reviews the arguments both for and against. Peter H. Schwartz, MD, PhD, explains that giving patients quantitative information on risk during the process of obtaining informed consent may contribute to their over- or underestimating the risk in question, distorting their ability to decide between treatments.

Several other contributors discuss challenges and alternatives to classical, autonomy-focused informed consent. Steven D. Freedman, MD, PhD, and Camilia R. Martin, MD, MS, point out that merely opening health-system electronic medical records to

patients will not help them interpret, understand, or remember the relevant information; health record systems intended to facilitate shared decision making must be designed for that specific purpose. Sorcha A. Brophy reviews a survey of physicians that found a gap between some physicians' stated beliefs about disclosing information to patients and their behavior, concluding that more research is needed into the particular circumstances and relationships surrounding these behaviors.

In an op-ed article, Brian C. Drolet, MD, and Candace L. White, MD, MA, argue that shared decision making is not always possible—patients may lack sufficient health literacy to be equal partners, physicians and patients may be unable to agree, and surrogate decision makers may be overwhelmed. They conclude that paternalism, used selectively and sensitively, may sometimes be appropriate. Similarly, in his case commentary, J. Randall Curtis, MD, MPH, proposes an alternative to explicit informed consent for situations in which surrogate decision makers for ICU patients must consider withdrawing certain treatments. Dr. Curtis argues for the use of "informed assent" in certain settings where making difficult decisions about ending futile care for their loved ones is a significant burden to families. In this way, we see that care centered on patients' and families' decisions does not just involve considering the type of information disclosed but also the degree of involvement that is required.

In the medicine and society section, Judith A. Hall, PhD, reframes what it might mean for physicians to train and practice patient-centered care. In her vision, further work would be put not only into training clinicians to express compassion, as is commonly done in medical schools, but also into improving their receptiveness to patients: to build better relationships through reading patients' emotional states, concerns and preferences, even when not verbalized. Steve Crossman, MD, discusses one method of helping student clinicians develop this receptiveness: Balint groups, in which medical student group members describe a difficult patient relationship, and other participants put themselves in the shoes of patient and student, thus strengthening all students' empathic response to patients.

Finally, Allan Ramsay, MD, a family physician in Vermont who has made the transition from clinical practice to membership on the board responsible for designing the nation's first single-payer health system. In an interview, Dr. Ramsay discusses the crucial role of another party in patient-physician decision making: the government. Ramsay's comments are a powerful reminder that changing medical practices in the doctor's office requires the support of policy reform.

This issue again and again speaks to a common theme: truly putting the patient at the heart of decisions is a much more nuanced and less formulaic endeavor than it may initially seem, and doing so can profoundly transform medicine for both patients and clinicians. As Dr. Hall points out, improving shared decision making expands the ethical duties of physician to obtaining as much understanding about our patients as possible; it shifts the physician role from simply providing treatments with some patient input to building relationships. It is from this subtler, more sophisticated

perspective that, I hope, we physicians may also benefit, experiencing a more satisfying and enriching practice of medicine in which both our humanity and that of our patients is better realized.

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ETHICS CASE
Discounting a Surgical Risk: Data, Understanding, and Gist
Commentary by Peter H. Schwartz, MD, PhD

Dr. Feng had purposefully scheduled Ms. Reid to come into the office at 4:15 PM on a Friday. Despite the fact that her office staff would be trying to make it home as soon as possible, Dr. Feng had imagined that Ms. Reid might need extra time to discuss her biopsy results: there was a chance that the lump on her neck that she'd felt when tying a scarf might be cancerous.

Ms. Reid had been in the waiting room for an hour already by the time Dr. Feng called her in, trying to keep an eye on her two young sons, who were tipping over towers of cardboard blocks into the aisles between seats.

"Well, Ms. Reid," Dr Feng started. "I'd hoped that we'd have a clearer answer for you today, but the pathology results from the aspiration of thyroid nodule are unclear. Some of the cells do look concerning for malignancy. We could repeat the aspiration, but I think that we should remove a piece of your thyroid at this point, to be safe."

"Is this a big surgery? Do I have to stay in the hospital?" Ms. Reid asked. With her job as a teacher and her kids, an inpatient stay would be difficult.

"No, no. It's a day surgery, and one I do routinely. The complications we might see are mainly bleeding and infection. We can control bleeding by cauterizing blood vessels or tying them off, and if there are signs of infection, for instance, if the wound becomes red or if you begin to have fever, we will start you on an antibiotic. There is always a slight risk of injuring a nerve to your vocal chord, but I've done this surgery many times and that's very rare. What questions do you have for me about the procedure?"

Ms. Reid said, "I'm ready to have this lump gone. Let's go ahead with the surgery."

"OK, then, visit with the scheduling nurse out front, and set up a time that works for both of us. You might want to schedule it before one of those occasions when your school has a 3-day weekend, like Easter or Memorial Day. The surgery isn't urgent."

Mrs. Reid scheduled the surgery, and it went as planned.

A few days after the surgery, Ms. Reid came in for an emergency appointment with Dr. Feng. It was obvious that she was irate, but her voice could barely be heard above the noise of the clinic.

"I thought you said this was rare," she said, shaking a printout of a journal article on the subject. "My recurrent laryngeal nerve was injured. I'm a teacher, and I have children! I need my voice. I would have never done the surgery if I knew there was a 4 percent risk that I would lose my voice!" Was Dr. Feng negligent in explaining the risks of surgery to Ms. Reid? Was she required to use precise percentages of risk?

Commentary

Something went seriously wrong in the way that Ms. Reid chose to undergo surgery. But the problem was not necessarily that her doctor failed to tell her that there was a 4 percent chance of damage to her voice. The problem was that Ms. Reid did not understand that that this injury was a real possibility and that either of her options (surgery or further testing) carried complex risks and benefits. Disclosing the exact probability of the injury and other possible outcomes might have helped her, and other patients, make a good decision, but it can also hinder that process. Research has shown that quantitative information can confuse and mislead as well as inform, challenging the assumption that disclosing such information is always ethically required [1].

The Complexity of the Decision

During her meeting with her doctor, Ms. Reid must decide whether to have surgery immediately or postpone it and pursue more testing, most likely another fine-needle aspiration. The choice is not a simple one.

The benefit of having surgery is finding out definitively whether there is cancer in the nodule and, if there is, taking care of the problem (unless it has already spread, which is unlikely). At the same time, the surgery carries risks, including the damage Ms. Reid suffered to her voice but also other dangers, such as bleeding and infection. Although the doctor downplays these, they may of course be significant.

The main benefit of putting off the surgery is that further testing could show that there is most likely no cancer, allowing Ms. Reid to avoid undergoing surgery. In fact, she might benefit even if the testing shows a high chance of cancer, if it eases her decision about having surgery and thus reduces the likelihood of regret over negative outcomes, such as the one she experienced.

The downsides of pursuing more testing are the time, discomfort, and other burdens of the procedure, as well as the usual chances of bleeding and infection. Importantly, there is always the possibility that the testing will not clarify her risk. Also, even if the additional testing indicates that the chance of cancer is low, allowing her to avoid surgery, the nodule will still need to be checked by ultrasound 6 to 18 months later, and then in 3 to 5 years, according to standard guidelines [2]. If certain types of growth have occurred at these times, more testing and possibly surgery would be needed. It's especially important to remember that any biopsy can fail to identify some cancerous or precancerous cells that can become a problem in the future—the so-called risk of a "false negative."

Given all this, a significant downside of undergoing more testing rather than surgery is that Ms. Reid will need to live with at least some uncertainty, possibly for an extended period. The surgery has the benefit of providing certainty. In fact, this appears to be a key motivation for both Dr. Feng and Ms. Reid, as when she announces her decision with, "I'm ready to have this lump gone."

The Advantage of Giving the Numbers

As we know from the case, things did not turn out well, and Ms. Reid complains that she would never have had the surgery had she been told that the risk of injury to her voice was 4 percent. She feels that Dr. Feng's description of this side effect as "rare" led her to underestimate its importance. Interestingly, when the European Union issued guidelines for using words to convey risk, they pegged the word "rare" to a risk of 1 in 1,000 to 1 in 10,000 [3], much lower than the risk that Ms. Reid faced.

At the same time, studies show that laypeople associate the word "rare" with probabilities that are much higher than the numbers favored by the EU, often equal to or greater than the 4 percent risk of the injury that Ms. Reid suffered. Subjects in one study guessed that the "rare" side effect of a hypothetical medication would occur 0 percent to 70 percent of the time, with about half of the individuals choosing a number between 5 percent and 20 percent [3]. Another study found that patients came up with a similarly wide range of interpretations for words like "rare" and "likely" when applied to the risks of surgery [4].

Due to the variable understanding of such words, many experts have argued that patients should always be given the numbers instead [5-7]. These experts reason that patients should receive full information and make their own determinations about whether a risk is "rare" or not, as part of a process leading to an autonomous decision.

To clarify the ethical issues, it is helpful to consider two criteria for what should be disclosed during informed consent. The *subjective standard* requires that each patient should be given all the information that he or she would find important in making the decision at hand [8]. Ms. Reid says that she would have found the 4 percent risk relevant, so, according to the subjective standard, it seems she should have been told of it.

The subjective standard has been criticized as being unfair to clinicians because it requires them to determine exactly what information each patient wants. This problem has led many to prefer the *reasonable person standard*, which requires only that the clinician should disclose the information that a reasonable patient would want [8]. Still, given the research about variable interpretation of words like "rare," it seems that the reasonable person standard would require disclosure of the specific risk of 4 percent.

The subjective standard and reasonable person standard help clarify the ethical basis for Ms. Reid's complaint, but they also provide a framework for exploring its weaknesses [9].

Numeracy, Heuristics, and Biases

The idea that a *reasonable person* would want to know the specific probability of the risk raises the question of whether such a person would be able to understand the number. Studies show that more than 20 percent of adults in the United States have only basic mathematical skills like counting and another 33 percent are limited to simple arithmetic. Less than 50 percent of adults comprehend the more complex mathematical concepts of frequency and percentage that are central to probability [10, 11]. One could argue that we cannot assume that the "reasonable" person is numerate and thus cannot conclude that the reasonable person standard requires disclosure of such information [1].

Even those who understand probability may irrationally discount a risk such as 4 percent. For example, when told that a negative outcome will be suffered by 4 out of 100 people, some people will be unreasonably confident that they will *not* be one of the unfortunate ones due to the "optimism bias" [12]. Psychologists and economists have demonstrated a large number of such "heuristics" and "biases" in human thought, often related to rare outcomes. For instance, when making a decision, people often fail to account for the difference in importance of an event that will occur 1 in 1,000 times and one that will occur 1 in 100 times [13].

Other research has shown that people respond to probabilistic information differently based on how it is described or framed even when those descriptions are mathematically equivalent. For instance, people interpret a danger as being more likely when it is stated using positive framing (e.g., saying that 4 percent will experience it), than when stated using negative framing (e.g., saying that 96 percent will not experience it) [14]. Some guidelines recommend that doctors provide both positive and negative framing of outcomes to avoid causing bias [15]. This approach, however, can be quite confusing, especially for those who have limited numeracy, and presenting the negative framing allows people to focus on the chance that the risk will not occur, resulting in the optimism bias.

Emphasizing a Risk and Balancing Risks

If Dr. Feng wanted to make sure that Ms. Reid understood the risk of injury to her voice, she might have chosen to state its probability using only positive framing (4 percent) or employing other means to make sure that Ms. Reid takes the chance seriously. But the challenge is not just of making sure she recognizes the risk, but, more importantly, helping her comprehend the risk in a way that allows her to choose rationally between surgery and further testing.

And for her to do that, it appears that she must understand other probabilities as well, perhaps most importantly the chance that there is cancer present in her thyroid that could spread and prove lethal. The case doesn't tell us the probability of this

outcome but, given what her doctor says, the finding on her initial biopsy could have been "follicular lesion of undetermined significance," or something similar. According to the literature, this finding carries a 5-10 percent chance of malignancy [16].

Other numbers that are clearly relevant include the probabilities that the repeat testing will show that there is minimal chance of cancer (and thus that she can forgo surgery without concern) or produce no change in the risk estimate (leaving her with the same uncertainty about how to proceed) or show that there is probably cancer present (and thus that she should have surgery). Further, if the biopsy is reassuring, it would seem important to know the chance of a false negative, i.e., her chance of facing further problems with thyroid cancer.

If before the operation, Dr. Feng had disclosed the exact chance of damage to Ms. Reid's voice, it appears she should have provided these other probabilities as well, in a way that allowed rational evaluation and balancing among them. But it is unclear how she should do this, given the existence of widespread innumeracy in the population and common heuristics and biases in human thought [17]. Finally, she may not even have good numbers for some of these possible outcomes—such as whether the further testing will help clarify Ms. Reid's risk—or what the chance of a false negative would be.

Conclusion

These considerations suggest that disclosing a specific probability of a risk is less important than helping patients understand that there is a difficult decision to be made, and comprehend in some way the sort of complex and incommensurable tradeoffs involved. Providing exact numbers is not clearly required or even helpful for specific patients or overall, for a theoretical "reasonable person."

This conclusion fits with "dual process" theories of human thought about risk, which hypothesize that *verbatim memory* encodes specific numbers, while *gist representations* classify outcomes in terms such as "important," "rare," and so on [18]. According to dual process accounts, gist plays a much more important role in decision making than verbatim memory. And from this perspective, the questions of whether doctors should disclose numbers and when depend on whether doing so can help patients form accurate and effective gist representations.

Finally, the process of informing a patient and explaining that a difficult decision must be made is not equivalent to demanding she make the decision alone. If Ms. Reid understood the complexity of the tradeoffs involved in her surgery, it is possible that she, like many patients, would ask the doctor what she recommends [19]. In fact, Dr. Feng provided her recommendation in a thinly veiled and persuasive way, with her interpretation of the risks and benefits of surgery. But she failed to emphasize the existence of a difficult choice to be made, and thus she failed to give Ms. Reid a chance to make her own decision, or to decide in an informed way

to rely on the doctor's recommendation. Her failure to disclose the specific probability of damage to Ms. Reid's voice was not the problem.

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ETHICS CASE
When Patients Seem Overly Optimistic
Commentary by Jane deLima Thomas, MD

Dr. Beard was not surprised to see that Mr. Cohen leaned heavily on an ornately carved cane to walk the long corridor to her office. She had just been looking at images of his spine, to which his pancreatic cancer had now metastasized, sprinkling a long stretch of his lumbar spine with ominous grey holes.

Mr. Cohen had previously asked that Dr. Beard be direct with him, so she began as soon a she was settled in the chair in her office. "As you had been guessing from your new back pain, it looks like the cancer has spread to your spine."

"I'd thought so," said Mr. Cohen. "I've been reading more and more about new treatments, and I really think it'll work out fine. I've just started a new chemotherapy, and I have a big trip planned around the world for next year. Besides, this is a great hospital, and I know you're the best in the field."

Dr. Beard hesitated. She had not anticipated this level of optimism. Mr. Cohen had been diagnosed 6 months before. Since then, several chemotherapy protocols had failed to reduce his tumors, and he was increasingly crippled by the metastasis.

"I'm glad you're thinking so positively," Dr. Beard said carefully. "But your disease is moving much more quickly than I'd expected. These CT scans show that it is now in your spine."

"Oh, I know. But the more I read about these new treatments, I really think it's all going to work out fine," Mr. Cohen repeated. "Besides, if I don't hope for the best, well...." His voice trailed off.

Later that day, Dr. Beard received a concerned phone call from Mr. Cohen's daughter, a nurse in the ICU.

"Dr. Beard, I know what this disease is like, and it's clearly progressing. My father's not getting it. You need to make sure that he understands the reality," she said.

Commentary
The situation described in this case is not uncommon for clinicians who work with patients with life-limiting illness. The clinician has done the difficult task

of giving bad news, but the patient continues to express unrealistic optimism. What responsibility does the clinician have to make sure the patient accepts the gravity of the illness? What are the risks and benefits of being more explicit with the patient about the seriousness of the illness as opposed to allowing him or her to hold on to unrealistic hopes?

Clinicians often feel that the ethical precept of respect for patient autonomy requires that patients not only hear prognostic information but accept it in order to participate fully in making decisions. This approach has limited utility, however, since some patients cannot understand or come to terms with a poor prognosis for a variety of reasons [2]. In these cases, shared decision making is best done using a patient-centered approach, which involves making a careful assessment of the reasons a patient seems not to accept the prognosis, weighing the risks and benefits of being more explicit, using patient-centered communication skills to convey the information in a way that patients are more likely to accept, and using surrogate decision makers when necessary. What follows are four questions to consider when faced with a patient who seems not to accept a poor prognosis.

1. What is the patient's true understanding of the illness?

   Sometimes patients receive direct information about prognosis but still don't understand. This can happen for several reasons, including underlying cognitive deficits, language barriers, medical illness (e.g., delirium), or the use of jargon or euphemisms by the clinician. A patient may have an underlying undiagnosed neurologic issue like mild dementia that is exacerbated by acute illness and interfering with the ability to process and remember information. Other patients may be cognitively intact but have emotional barriers to processing medical information. For example, one study showed that patients who did not acknowledge their prognosis had rates of depression nearly three times higher than those who did [1].

   Assessing the patient's understanding and barriers to understanding is the first step in trying to decide what information still needs to be shared and the most effective method of sharing it. Is there need for an interpreter? Are there underlying medical illnesses that must be addressed first? Would emotional overload preclude giving more information? And if the barriers to understanding are insurmountable, does the patient have capacity to make decisions, or should a surrogate decision maker or health care proxy be involved? Answers to these questions help the clinician understand the patient's ability to process information and guide the plan for next steps.

2. If there are no barriers to the patient's understanding prognostic information, are there specific reasons that he or she continues to appear hopeful?

   There are several reasons why patients may continue to express optimism even as they seem to understand that the illness is serious. Some may be protecting family members, putting up a good front so that loved ones won't worry that they are sad or afraid. Other patients express hopefulness for fear that the clinician may stop trying to treat the disease if they express doubt that the treatments will work. Yet others may be responding to social pressure to avoid the appearance of "giving up," which can seem self-sabotaging or even suicidal. Lastly, most patients find it impossible to live with the reality of impending death at every moment and oscillate between realistic acknowledgement of the gravity of the illness and optimistic hopes. For most patients, this is simply a manifestation of healthy coping as they adjust to a new and difficult reality, although it can give the impression that they are in complete denial if clinicians only see them at moments of hopefulness.

3. What is at stake if the patient does not recognize the seriousness of the illness?

   The answer to this question should be an important consideration when clinicians are deciding how much to push patients to acknowledge the seriousness of their prognosis. The baseline assumption—and what the data about good end-of-life care and bereavement outcomes shows—is that patients and their families have better outcomes when they are given the opportunity to prepare for the losses associated with advanced illness and death.

   Even with that understanding, however, clinicians faced with patients who refuse to accept the gravity of their illness should pause before launching into a serious discussion about prognosis and ask themselves, "What good will come of having a frank discussion? What harm?" Clinicians should ensure that the motivation for discussing prognosis further is not simply to ease their own discomfort. Factors that might justify giving patients more leeway to sustain unrealistic hopes include a gently declining clinical course, a patient's emotional fragility, or a code status that is already consistent with the patient's values. Factors that might compel clinicians to be more explicit include a rapidly deteriorating clinical status, unresolved issues with high potential for harm (e.g., unclear guardianship for children or a family that is unprepared for the death), or a code status that is inconsistent with the patient's values.

4. How can clinicians proceed if—after they have considered questions 1 through 3—they feel the patient will come to harm if he or she does not understand the reality of the poor prognosis?

   After assessing (1) obstacles to the patient's understanding, (2) reasons for continued unrealistic hopefulness in the face of clear understanding, and (3) the risks to the patient if he or she holds on to unrealistic optimism, clinicians may believe that significant harm will come to the patient if he or she does not acknowledge the seriousness of the illness. Often specific patient-centered communication skills can be helpful in those situations.

   Using "hope and worry" statements can help preserve alignment with the patient even as difficult news is being discussed, e.g., "I hope we can find a way to stop the progression of your disease but I worry that we are seeing that it isn't possible." Using "I wish" statements can serve a similar purpose, e.g., "I wish we had an effective treatment for your disease but it looks like nothing we have used is working any more." Using hypothetical questions can sometimes give patients an opening to talk about the reality of the situation, e.g., "Have you ever thought about what would happen if the disease weren't treatable?"

   Lastly, "naming the dilemma" can be helpful if the first three techniques are ineffective, e.g., "I find myself in a tough spot. I want to give you the very best care, but I am concerned that I won't know how to do that if we don't talk about what's happening with your illness. Do you think we could do that?"

   If patients persist in avoiding facing a poor prognosis despite the likelihood of harm if they continue to do so, clinicians can ask for permission to talk with surrogate decision makers. "I understand that it can be very difficult to talk about things going badly. I don't want to force you to do something you feel isn't right for you, but there are some decisions that have to be made. Is there someone you have named to make decisions for you if you can't or choose not to? Would it be OK with you if I talk to that person so we can think together about how to ensure you receive the best care?"

In summary, clinicians faced with patients who hold on to unrealistic hopes in the context of serious illness often worry that they are responsible for ensuring that the patient accepts the gravity of the prognosis. The above considerations shift the nature of that responsibility. Clinicians are responsible for the following:

- Identifying and—to the extent possible—removing barriers to a patient's understanding;

- Assessing reasons patients may hold on to unrealistic hopes despite clear understanding;
- Evaluating the risks and benefits to the patient of having more frank discussions about prognosis;
- Using patient-centered communication skills to try to offer information about prognosis in order to prepare the patient for continued decline; and
- Trying to obtain permission to use a surrogate decision maker if time is short and decisions need to be made.

Clinicians should also recognize that patients' acceptance of poor prognosis is a dynamic state that changes over time. They would do well to revisit the conversation at different points in the course of the illness to give patients the opportunity for discussion as they adjust to the progressive nature of the disease. Clinicians who follow these steps, however, have fulfilled their ethical obligation to respect patient autonomy and need not feel they have failed the patient if he or she continues to refuse to acknowledge a poor prognosis. In that case, good patient care includes respecting a patient's autonomy in deciding *not* to acknowledge it.

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ETHICS CASE

The Use of Informed Assent in Withholding Cardiopulmonary Resuscitation in the ICU

Commentary by J. Randall Curtis, MD, MPH

Ms. Rose's family had gathered in the intensive care unit conference room. Her three sons and daughter all looked haggard; their mother's advancing lung cancer had led to a long stay in the intensive care unit (ICU). This was the second conference since their mother was intubated a week before. After that meeting, she'd done well with treatments, and the breathing tube had just been removed, although she was still drifting in and out of consciousness. However, the last few days had been increasingly difficult, and, although Ms. Rose's lung function was improved, she was no longer aware of what was going on around her. Her heart had weakened, and her blood pressure had slowly been dropping despite medications.

During the first meeting, it had been easy for the siblings and the ICU attending physician, Dr. Branson, to come to an agreement about a plan. They would put her on the ventilator to see how her lungs responded and would keep her as comfortable as possible, hoping that she could soon recover and get home to enjoy her flower gardens and visits from her many grandchildren.

By 9 AM after their long week, many of the siblings were sipping coffee from styrofoam cups, as they chatted with the chaplain, social worker, and nurse who had also gathered for the meeting. As Dr. Branson entered, the room hushed a little. Despite the long course of Ms. Rose's worsening pulmonary condition, her family braced for the coming conversation.

"Thanks to all of you for making it in," Dr. Branson started. "As I've discussed with many of you day to day, your mother continues to get sicker. She did well last week after a short amount of time on the ventilator, but the cancer keeps spreading and she's getting weaker. At this point, I worry that giving her CPR will not improve her chances of ever leaving the hospital and it'll cause her a lot of discomfort. My understanding from all of you is that what matters to her is being up and busy and taking care of the people in her life. It sounds like she would not want to be resuscitated if it meant that she would likely never leave the ICU, much less the hospital." He paused and looked around the room. Several of Ms. Rose's children looked at him and nodded slightly. After allowing a few moments during which no one spoke, Dr. Branson said, "Unless anyone disagrees, I'd like to write in her chart that if her heart stops, she not be resuscitated."

After answering some questions from the family, he wrapped up the meeting. A few minutes later, the nurse who had been in the family meeting approached him. "You didn't give the family a chance to choose," she said angrily. "You just decided for them. What if after CPR she bounces back? It's happened before."

Commentary

There is growing consensus on the importance of shared decision making in the intensive care unit (ICU) [1]. At the same time, however, there is an active debate over the appropriate role of unilateral decisions on the part of physicians to withhold or withdraw life-sustaining treatments because they would be medically futile [2]. The use of unilateral decision making to withdraw life-sustaining treatment has recently been brought into the spotlight in exchanges about the Texas Advance Directives Act [3, 4]. There have been cogent descriptions of the rationale for using the principle of medical futility to guide unilateral physician decision making [5, 6] and evidence that the futility rationale is used in clinical practice in the U.S. [7] and around the world [8]. However, there have also been compelling arguments made against the use of the futility principle [9-11]. In the U.S., there is not currently a consensus in medicine about the use of unilateral physician decision making concerning medical futility.

Professor Robert Burt and I have articulated an approach we have called "informed assent" that may be a reasonable alternative to unilateral decision making by physicians over the objections of family members [12]. There are specific (and relatively rare) circumstances in which some therapies that are commonly expected by family members, such as CPR, are exceedingly unlikely to provide any benefit to the patient. In these circumstances, many have argued that clinicians are not obliged to obtain informed consent to withhold or withdraw the therapies [13]. In fact, the process of obtaining informed consent may cause considerable distress for some family members: if a therapy is not indicated but we insist on requiring family members to actively refuse it, we may increase their burden of guilt.

There is compelling evidence of anxiety, depression, and posttraumatic stress disorder among family members of critically ill patients [14-17]. Observed risk factors for these psychological symptoms include any one of the following: family involvement in decision making [15], family preference for less involvement in decision making [18], and a family role that is discordant with its members' preferences [19].

Therefore, we have argued that obtaining "informed assent"—in which the family is explicitly offered the choice to defer to clinicians' judgment about withholding or withdrawing life-sustaining therapy—may be an appropriate and ethical alternative to requiring informed consent. In the application of informed assent, we believe that clinicians should provide full information about the risks and benefits of expected or requested treatments, convey specific recommendations about the medically proposed course, and clearly indicate that the patient and family are being invited to defer to the clinicians' judgment. This is similar to the conventional conception of

informed consent—an informed patient or family member can always make an affirmative choice to accept clinicians' recommendations. But, by not asking the family to formally consent to the decision, the informed-assent approach avoids putting family members in the difficult position of feeling responsible for the outcome.

High-quality communication about withholding and withdrawing life support in the ICU does not assume that one size fits all; an important aspect of this communication is to determine the role individual family members want to play in such decisions [20]. Some want to be centrally involved in all decisions and others want to defer such decisions to the clinicians [19, 21]. There are family members who will be greatly relieved that clinicians are willing to take responsibility for decisions, for example, to withhold CPR when it is not indicated. These family members may accept a clinician's determination that CPR is not indicated, but they may find it extremely difficult to feel that they are personally deciding to withhold CPR from their critically ill loved one. There are also family members who will feel that being involved in such decisions allows them to give an important gift to the critically ill patient by taking personal responsibility for ensuring that his or her wishes are followed and best interests are advanced. It is the responsibility of clinicians to determine where on this spectrum individual family members fall and to communicate and share decision making accordingly.

In my experience, most family members have deferred to my judgment when I used an informed-assent approach. Some family members, of course, have not. Often, the latter will respect and appreciate my clinical expertise, but don't concur with my assessment that the treatment is not indicated.

When families disagree with clinicians' judgment and request the therapy that is not being offered, my approach is generally not to unilaterally refuse to offer CPR. I believe that this causes more harm than good, interfering with our relationship and undermining the trust they have in me. The American Medical Association recommends that in this situation a process be initiated to reconcile differences between clinicians and families and that the treatment be offered until reconciliation is achieved [22]. That is the approach that I tend to take for CPR and for withdrawing ongoing life-sustaining treatment. There are, however, some resource-intensive therapies, such as extracorporeal membrane oxygenation, that I may unilaterally refuse to offer if I believe they are clearly not indicated, even if the family requests it.

I argue that the informed-assent approach is most fitting when family members expect or request that we offer or discuss a particular therapy, but it would be uncommon, unnecessary, and impractical to discuss all possible but nonindicated therapies in the ICU. Routine unilateral decisions about futility are an entirely appropriate use of medical judgment and consistent with good quality care, if the clinicians are careful in the determination that the treatment is not indicated and that the family does not expect or request the treatment. However, we argue that

clinicians are obliged to discuss such interventions when they are commonly expected (such as CPR) or specifically requested by a family. To avoid creating disparities based on different families' levels of health literacy, clinicians must be careful to apply this approach only to therapies that are not indicated.

The use of informed assent is a little more complex in the *withdrawal* of a therapy that is no longer indicated than for *withholding* CPR. Although many medical ethicists conclude that withholding and withdrawing life-sustaining treatments are ethically and legally equivalent, decisions about withdrawing interventions already under way have a more powerful impact on families (and many clinicians) than decisions not to initiate therapies in the first place. Accordingly, communication with families about withdrawal decisions should account for these differences. Clinicians should assume that patients or families expect interventions to be continued and discussions should be thorough and careful.

Informed assent should not be used when clinicians are uncertain about the possibility of success or when the clinicians' convictions about withholding or withdrawing treatment are based on their value judgments about the patient's future quality of life. Such judgments are insufficient grounds for declaring that the therapy is not indicated. Consequently, clinicians may express their opinions and recommendations about the treatment options, but should make clear that these recommendations are based on value judgments and explain them.

Based on the description of the case of Ms. Rose, Dr. Branson seems to have taken an informed-assent approach. To do so ethically requires attention to the preferences and needs of individual family members; to be confident that Dr. Branson's approach was appropriate, we would want to be sure that the family understood his rationale for withholding CPR and that his communication—both verbal and nonverbal—left open the opportunity for the family to actively disagree with the order not to resuscitate. Used properly, informed assent may be an appropriate alternative and may protect some families from the potential burden of feeling responsible for a decision to withhold or withdraw a therapy that is not indicated.

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MEDICAL EDUCATION

Investing in Each Other—Balint Groups and the Patient-Doctor Relationship

Steve Crossman, MD

Have you ever felt dread or fear at the thought of opening the door to see a patient? Has an overwhelming feeling of despair or frustration suddenly come upon you after seeing certain names or your appointment list for the day? Do you ever feel too close, too connected to a patient and worry about keeping your distance? If none of this sounds familiar—then just wait, because it will. If you have experienced such feelings, does it make you an incompetent, unethical, or unprofessional physician or student?

I would like to open this commentary with a brief description of something extraordinary that is very rarely made available to medical students in their education. Here we go.

Pete was standing outside room 10-312 doing whatever he could to delay opening the door and greeting Mr. Smith, who had been on his service for 2 weeks now with no discharge in sight and whom he dreaded seeing. Thank goodness for e-mail—one of the best ways ever invented to procrastinate. A reminder e-mail for the group meeting that afternoon appeared on the screen of his phone. Nothing else new. Feeling too guilty to launch into a quick game of solitaire, Pete finally knocked on the door and pushed it open, forcing himself to smile when he said good morning to the patient waiting inside.

As he was checking e-mail for the last time before leaving the hospital, he once again saw the reminder for the group meeting. Kicking himself for not waiting until he got home to check, he made the hike over to the Department of Family Medicine and took the elevator up 14 floors. Pete was actually relieved to sit down in the circle of chairs amongst his peers and faculty.

When Dr. Crossman asked for a case, all of a sudden Pete sat up, leaned forward and claimed the moment to discuss his relationship with Mr. Smith,. Pete did as he was asked, minimizing the clinical facts of the case and instead focusing on his feelings about Mr. Smith. He was surprised to find himself telling the group about his dread and his sadness and his fear. Thankful to be done, he scooted his chair back and listened for the better part of 45 minutes while his peers put themselves in both Pete's and the patient's shoes, describing how each would feel in the relationship described.

Pete left the group feeling supported and comforted, but more than that, excited to see Mr. Smith again. The next morning outside of room 10-312, Pete felt hopeful. He didn't look at his phone once before knocking on Mr. Smith's door.

During their preclinical years, medical students are indoctrinated in standards of professionalism and the principles of medical ethics. While professionalism standards may vary some by institution, the ethical principles are clearly, and in the United States explicitly, defined by Thomas Beauchamp and James Childress. These four principles of medical ethics are:

> (1) Beneficence—obligations to provide benefits and to balance benefits against risks; (2) Nonmaleficence—the obligation to avoid causing harm; (3) Respect for autonomy—the obligation to respect the decision-making capacities of autonomous persons; and (4) Justice—obligations of fairness in the distribution of benefits and risks [1].

However, it is much more difficult to implement these principles when every physician, every patient, every relationship is unique, and when perspectives are so different. Applying these four straightforward ethical principles then is crucially dependent upon context. Returning to Pete, what did he experience that allowed him to become unstuck in his relationship with this patient? In other words, what was it that allowed him to step beyond himself and his reactions to Mr. Smith and enabled him to return more fully to his professional role as healer? It was a Balint group.

Michael Balint (1896-1970) was a Hungarian-born psychoanalyst who spent decades exploring the nature and power of the patient-doctor relationship. His name has become synonymous with a group process through which health professionals and health professional trainees can gain a better understanding of and ability to use the patient-doctor relationship to provide ever better care. Balint groups are ongoing around the world; in the United States they have been used primarily during residency training, initially in family medicine but now in many other disciplines as well.

Dr. Balint's most famous work, *The Doctor, His Patient and the Illness,* was published in 1957 [2]. I was amazed when I first read this book, nearly 50 years after it was published, at how the dilemmas described by doctors in England in the 1950s were so very similar to much of what I struggled most with in my own practice in rural Virginia. The aspect of the book that resonates most with me is Dr. Balint's description of the doctor-patient relationship as a "mutual investment company." In this relationship-as-investment-company analogy, physician and patient each contribute with the implied expectation of mutual gain: the physician wants to help the patient and make a living and the patient wants to feel better.

The invested assets of physician and patient are acquired cautiously over time and then must be carefully managed if the full return is to be achieved. As with any long-term investment, over time the doctor and patient need to add to, borrow from, and

lend their assets. A strong and stable investment history builds trust and confidence that allow risks to be taken. This confidence and trust also allows short-term stress and volatility to be accepted and weathered without any lasting harm. The result of sound investing and careful cultivation is a powerful and meaningful patient-doctor relationship.

The process of the Balint group is straightforward. There are three steps: case presentation, clarification of facts, and speculation regarding what might be happening in this relationship. A group member presents a challenging case. The challenge, rather than being a clinical question of what test to order or what medication to prescribe, is a challenge concerning the ongoing relationship the presenter has with a patient. The presenter describes from memory the patient, the relationship, and the dilemma. There are no notes, no vital signs, and no lab values involved. After this presentation, group members have the opportunity to ask questions to clarify issues of fact. Questions focus on things such as the patient's age, the patient's family structure, or whether the patient has a job.

After that, the presenter's work is done, and she is asked to sit back and reflect on what is said as the group works through the case. Group members begin to speculate by putting themselves, in turn, into the shoes of the patient and the student or physician described in the presented case. Using "I" statements, group members express what they would be feeling if they were the patient or caregiver in the relationship.

In the scenario above, one group member might well describe how helpless and useless he would feel caring every day for this patient who was not getting better. Another group member would very likely note, as the patient, how much she values Pete's daily visits and how important it is to have someone on the medical team who comes in every day without rushing right back out. Trained group leaders facilitate the process, maintaining an environment of respect, ensuring confidentiality and safety within the group, protecting the presenter from being judged, evaluated, or pressured in any way, and carefully monitoring the discussion to be certain that both the physician and the patient are given due attention.

This patient-doctor relationship provides the context necessary for the best possible application of ethical standards. In today's challenging medical world where training and practice alike are being stressed by increasing standards for compliance, ever-expanding knowledge and technology, compressed in terms of both time and space, and compartmentalized (e.g., hospitalist, night float, and so on), ethical challenges are sure to increase. Balint groups give us a model and a process that, together, show us how to invest as much as we possibly can in our relationships with patients to create the context needed for delivery of the best possible care.

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THE CODE SAYS
The AMA *Code of Medical Ethics*' Opinions on Informing Patients

Opinion 8.08 - Informed Consent
The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent. In special circumstances, it may be appropriate to postpone disclosure of information (see Opinion 8.122, "Withholding Information from Patients").

Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients. Physicians need not communicate all information at one time, but should assess the amount of information that patients are capable of receiving at a given time and present the remainder when appropriate.

Opinion 8.082 - Withholding Information from Patients
The practice of withholding pertinent medical information from patients in the belief that disclosure is medically contraindicated is known as "therapeutic privilege." It creates a conflict between the physician's obligations to promote patients' welfare and respect for their autonomy by communicating truthfully. Therapeutic privilege does not refer to withholding medical information in emergency situations, or reporting medical errors (see 8.08, "Informed Consent," and 8.121, "Ethical Responsibility to Study and Prevent Error and Harm").

Withholding medical information from patients without their knowledge or consent is ethically unacceptable. Physicians should encourage patients to specify their preferences regarding communication of their medical information, preferably before the information becomes available. Moreover, physicians should honor patient requests not to be informed of certain medical information or to convey the information to a designated proxy, provided these requests appear to genuinely represent the patient's own wishes.

All information need not be communicated to the patient immediately or all at once; physicians should assess the amount of information a patient is capable of receiving at a given time, delaying the remainder to a later, more suitable time, and should tailor disclosure to meet patients' needs and expectations in light of their preferences.

Physicians may consider delaying disclosure only if early communication is clearly contraindicated. Physicians should continue to monitor the patient carefully and offer complete disclosure when the patient is able to decide whether or not to receive this information. This should be done according to a definite plan, so that disclosure is not permanently delayed. Consultation with patients' families, colleagues, or an ethics committee may help in assessing the balance of benefits and harms associated with delayed disclosure. In all circumstances, physicians should communicate with patients sensitively and respectfully.

Issued November 2006 based on the report "Withholding Information from Patients (Therapeutic Privilege)," adopted June 2006.

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JOURNAL DISCUSSION
Exploring Physicians' Attitudes about and Behavior in Communicating with Patients
Sorcha A. Brophy

Iezzoni LI, Rao SR, DesRoches CM, Vogeli C, Campbell EG. Survey shows that at least some physicians are not always open or honest with patients. *Health Aff (Millwood)*. 2012;31(2):383-391.

There is widespread agreement amongst physicians that openness and honesty are essential characteristics of communication with patients. However, even as these principles are foundational concepts of medical ethics and endorsed by various professional associations, adherence to them in clinical settings may vary. Few studies have explored how widely these ideas are accepted or practiced by physicians and how variations in beliefs and behaviors might be explained.

Iezzoni et al. explore these questions in their 2012 *Health Affairs* article [1]. The authors present data from a 2009 national survey assessing U.S. physicians' reported practices and beliefs regarding principles of the Charter on Medical Professionalism, which is endorsed by more than 100 professional groups and the U.S. Accreditation Council for Graduate Medical Education. The article reports results of a nine-question module intended to gauge attitudes and behaviors related to patient-physician communication.

Iezzoni et al. found strong evidence of broadly shared consensus about most of the attitudes measured: in general, respondents "completely agree" that physicians should fully inform patients of risks and benefits of treatment, never tell a patient something that is not true, and never disclose confidential patient information to unauthorized persons. However, the authors express concern about the greater variation in responses on disclosing medical errors and financial relationships with drug companies. More than a third of respondents reported that they either somewhat agree or disagree that physicians must disclose these things.

The national survey showed greater variation in how physicians *acted* than in their attitudes—in other words, a gap between beliefs and practices. More than half the respondents reported having described a patient's prognosis as more positive than evidence indicated [2], about 30 percent reported having (either accidentally or intentionally) revealed confidential information to an unauthorized person [2], and approximately 20 percent reported having not fully disclosed a mistake to a patient for fear of litigation [2]. In sum, the authors conclude that there is reason to be

concerned about the accuracy of information patients are receiving from physicians and, hence, in their ability to make informed health care decisions.

Iezzoni et al.'s article raises a number of questions about variation in the nature of interactions between physicians and patients and in the ethical concerns that exist about such interactions. These questions arise, in part, because of the scope of their physician-patient communication module—the module surveys a broad range of professionalism concerns and is intended to identify variations in adherence to professional norms, rather than explain why these variations exist.

The authors acknowledge the complexity that might underlie their findings—the physicians surveyed practice in a variety of interpersonal, cultural, and situation-specific contexts. However, it is also important to acknowledge that, even as these questions may, in aggregate, comprise meaningful facets of professionalism, they rely on a more individual and less coherent set of ethical concerns and responsibilities. There are qualitative differences in the ethical concerns that underlie these questions, such as the difference between willful disregard of professional norms and inadvertent mistakes (for example, between revealing confidential patient information intentionally or accidentally); the extent to which different types of communication are perceived to directly impact individual patient care (for example, fully informing patients of the risks and benefits of treatment versus consistently disclosing financial relationships with drug companies); and the difference between concealing treatment-related information for self-interested reasons (for example, financial incentives or fear of litigation) and concealing the same information out of concern for the patient (for example, in an attempt to protect the patient from emotional distress).

Iezzoni et al. measure responses to their questions about patient-physician communication attitudes and behaviors against a number of predictor variables that previous research has suggested explain differences in medical professionalism: respondents' sex, racial minority status (race or ethnicity other than white or Asian), years in practice, graduation from a medical school outside the U.S. or Canada, medical specialty, and practice setting. They also hypothesize a possible relationship between patient-physician communication and malpractice claims..

They found differences in communication attitudes and behaviors between sexes, racial groups, and medical specialties. The meaning of these differences is difficult to interpret—although members of underrepresented groups (women and racial minorities) were more likely to respond in compliance with professional standards, more than half of the differences were not significantly associated. Likewise, even when there were differences in communication attitudes and behaviors by specialty, the authors found no consistent patterns. With regard to the differences between responses by sex and race, Iezzoni et al. suggest that members of underrepresented groups may feel more pressure to comply with professional standards because of their more tenuous position within the field. Alternatively, it is possible that

members of underrepresented groups are more likely to report adherence to professional standards than members of historically dominant groups [3].

With regard to the differences in communication attitudes and behaviors by specialty, it is possible that future research about the qualitative variations in different types of communication experiences would help to make sense of these findings. By asking respondents to provide details about their experiences with patients, researchers might be able to categorize the various types of communication experiences by specialty and region into a parsimonious model.

Iezzoni et al.'s article provides substantial evidence that future empirical research about physician approaches to and experiences of patient communication is needed. Descriptive data about the nature of physician communication experiences would increase understanding of the relationship of physicians to professional standards and the role that professional standards play in determining behavior. Why do physicians engage in behaviors that appear to violate stated professional principles? A study designed to answer this question would help determine if noncompliance with professional standards is motivated by personal or ethical concerns, as well as determine whether there are alternative ethical commitments that may conflict with professional principles.

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1. Iezzoni LI, Rao SR, DesRoches CM, Vogeli C, Campbell EG. Survey shows that at least some physicians are not always open or honest with patients. *Health Aff (Millwood).* 2012;31(2):383-391.
2. Iezzoni LI, et al., 388.
3. The authors acknowledge the possibility of social desirability bias, however, they seem to assume that all groups are affected equally.

Sorcha A. Brophy is a doctoral candidate in the sociology program at Yale University in New Haven, Connecticut. Her research focuses on how ideas about morality and ethics diffuse throughout institutions and society.

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STATE OF THE ART AND SCIENCE

Do Patient-Accessible Electronic Medical Records Help Or Complicate Shared Decision Making?

Steven D. Freedman, MD, PhD, and Camilia R. Martin, MD, MS

As emphasized in the Patient Protection and Affordable Care Act (ACA), shared decision making is an important way of achieving optimal patient outcomes and respecting patients' right to choose their health care. However, time constraints have made the office visit a less-than-optimal environment for informed and effective shared decision making. The ideal is further compromised by many physicians' paternalistic concept of the patient-doctor relationship, in which doctors know best and patients adhere to their recommendations. The medical field will need to move away from this one-way conversation if we are to fully realize shared decision making.

As a result, it is critical to create an environment that facilitates shared decision making in the context of proliferating options (due to technological advances and personalized medicine) and escalating costs. The ACA states an intention to award grants and contracts for the creation of "patient decision aids,"

> an educational tool that helps patients, caregivers or authorized representatives understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences [1].

The act stipulates that patient decision aids shall,

> (A) be designed to engage patients, caregivers, and authorized representatives in informed decision making with health care providers;
> (B) present up-to-date clinical evidence about the risks and benefits of treatment options in a form and manner that is age-appropriate and can be adapted for patients, caregivers, and authorized representatives from a variety of cultural and educational backgrounds to reflect the varying needs of consumers and diverse levels of health literacy;
> (C) where appropriate, explain why there is a lack of evidence to support one treatment option over another; and
> (D) address health care decisions across the age span, including those affecting vulnerable populations including children [2].

In other words:

- *Patient decision aids must help patients access, understand, and use health information*. Key to this are both tailoring information to varying levels of health literacy and making sure that patients do not forget information.
- *This information must be evidence-based, current, and context-specific*. To be most useful, context specificity must include not only age- or disease-related information but also cultural practices and concerns.

Do current platforms achieve these goals? Presently, preexisting care-system electronic medical records (EMRs), such as MyChart and PatientSite, have added features that allow patient access. But these systems were originally designed as archives for health care professionals, not for use by patients, and they have limitations that prevent them from truly facilitating shared decision making. As intended uses change, so must the systems.

These preexisting EMRs tend to display information in a manner that is not easily viewed or deciphered by the patient. Access to information is generally grouped by category—such as labs, radiology, and office visits—rather than structured around medical problems or concerns. Reports often lack interpretations suitable for those with limited health literacy, especially for borderline lab results or incidental findings on imaging studies, and language can be highly technical. Further, appropriate educational content is lacking.

Solutions

Solutions must start from the premise that the physician and patient should be informed *joint* partners in setting the care plan. It is a process that begins with the initial encounter with the clinician but continues beyond the office visit. To be optimally supportive, information should be organized by medical concern and include educational material for both physicians and patients.

Moreover, this information must reflect best practices and be generated from an unbiased, vetted source. What if a physician is not up to date on a topic relevant to a patient's situation such as an alternative or complementary treatment? Patients commonly seek help on the Internet, but this information is frequently not vetted or effectively distilled.

An EMR that facilitates shared decision making must allow and show in real time adjustments in the care plan that everyone can see. In the process of building this digitized roadmap together, the patient's thoughts and beliefs are heard and integrated into an interactive document that is a source of actionable intelligence. Ideally, this permits the patient access to his or her health data and educational information specifically calibrated to his or her needs and to give others, such as friends, family members, health advocates, and other members of the health care team permission to view the plan. This protects the patient's privacy while giving the opportunity to remove hindrances to care that arise from information not being shared with family members and others. Clinicians can track a patient's progress,

intervene when necessary between office visits, identify health care barriers and best practices, and receive educational content at the point of care.

As happens when following any roadmap, bumps in the road will be encountered and directions may need to be changed. But that will occur most effectively through collaborative, informed decision making. Replacing the physician with a computer is not the answer, but developing electronic solutions to support and enhance decision making is a step in the right direction.

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HEALTH LAW

Informed Consent: What Must a Physician Disclose to a Patient?

Bryan Murray

Informed consent is at the heart of shared decision making—a recommended approach to medical treatment decision in which patients actively participate with their doctors. Patients must have adequate information if they are to play a significant role in making decisions that reflect their own values and preferences, and physicians play a key role as educators in this process.

Many patients may have a limited understanding of medicine, so it is difficult, if not impossible, for a physician to confirm that a patient has given adequately informed consent. Hence, it is almost self-evident that adherence to the doctrine of informed consent requires a physician to disclose enough about the risks and benefits of proposed treatments that the patient becomes sufficiently informed to participate in shared decision making. A practicing physician may find it difficult to strike a balance between too much and too little information. This article will discuss legal standards that define what types of risk and other information a physician must disclose in facilitating informed consent, as well as disclosures that are not legally required.

Informed Consent

The legal doctrine of informed consent can be traced back to the post-World War II Nuremburg Code, a set of guidelines drafted to ensure that unethical "medical" experiments were no longer carried out in the name of science. The doctrine is founded on the general principle that a person of the age of majority and sound mind has a legal right to determine what may be done to his or her body [1]. Thus, when a patient is subjected to a procedure he or she has not agreed to, the physician performing that procedure is violating the patient's legal rights and may be subject to medical malpractice litigation, removal from preferred-provider lists, or the loss of hospital privileges.

To avoid legal action, according to the doctrine of informed consent, physicians must disclose enough information for the patient to make an "informed" decision. However, because informed consent laws and principles do not specify the amount of information that must be disclosed, physicians might find it useful to know what they must typically disclose.

Traditionally, courts held that a physician's duty to disclose information to the patient depended upon community disclosure standards—whether the majority of physicians within a particular community would customarily make such a disclosure

[2]. More recently they have acknowledged problems with the community disclosure standard, chiefly that it creates an incentive for physicians to protect themselves by collectively limiting the standard disclosures, which is not in patients' best interests. In effort to address this problem, the D.C. Circuit Court of Appeals dramatically altered the physician's duty to disclose in the seminal case *Canterbury v. Spence* [3].

In *Canterbury*, a young man was advised by his physician to undergo a laminectomy in an effort to alleviate back pain. The physician, aware that 1 percent of laminectomies resulted in paralysis, did not advise the patient of the risk because he believed this might cause the patient to reject the useful treatment. Following the procedure, the patient fell from his hospital bed and was paralyzed. It remained uncertain whether the laminectomy procedure or the patient's fall caused the paralysis.

The patient sued, alleging that the physician failed to inform him of the risks associated with the procedure. The court held that "the standard measuring [physician] performance…is conduct which is reasonable under the circumstances" [3]. In other words, the court held that, instead of adhering to the community disclosure standard, *physicians are now required to disclose information if it is reasonable to do so*. Essentially, to establish true informed consent, a physician is now required to disclose all risks that might affect a patient's treatment decisions.

In *Canterbury*, the decision outlined key pieces of information that a physician must disclose:

> (1) condition being treated; (2) nature and character of the proposed treatment or surgical procedure; (3) anticipated results; (4) recognized possible alternative forms of treatment; and (5) recognized serious possible risks, complications, and anticipated benefits involved in the treatment or surgical procedure, as well as the recognized possible alternative forms of treatment, including non-treatment [4, 5].

In two informed consent cases following *Canterbury*, physicians have also been required to disclose (1) personal or economic interests that may influence their judgment (*Gates v. Jenson*) [6] and (2) all diagnostic tests that may rule out a possible condition (*Jandre v. Physicians Insurance Co of Wisconsin*) [7]. In *Arato v. Avedon*, however, physicians were not required to disclose particular statistical life expectancy rates to a patient suffering from pancreatic cancer, mainly on the grounds that statistics do not usefully relate to an individual's future [8].

The decision in *Nixdorf v. Hicken* stipulated that physicians must also disclose information that a reasonable person in the patient's position would find important [9]. In this case, a doctor left a surgical needle in his patient and was held to have a duty to disclose any information pertinent to the patient's treatment, including the patient's physical condition following treatment [9].

Similarly, a physician must also explain any benefits or risks that may be significant to the particular patient. For example, any risk of injury to a patient's hand is especially important to a concert violinist or professional baseball pitcher. In the briefest terms, a physician is required to provide general information about a proposed diagnosis or treatment and more personalized information about how the treatment might reasonably affect the particular patient.

Truly informed consent may also require disclosure of potential risks associated with not seeking treatment. In the California case *Truman v. Thomas*, in which a woman had refused a pap smear, the court held that a physician had a duty to disclose to her the possibility that precancerous cells might develop, uncaught, into cervical cancer if she declined to undergo the procedure [10].

Exceptions

While a physician is required to disclose all reasonable information, he or she is not required to disclose a risk that is not inherent in proper performance of the procedure—a risk, in other words, that would result only from the procedure's being performed incorrectly [11, 12].

The courts have noted two additional exceptions to the requirement that physicians elicit and document informed consent. The first applies when both (1) the patient is unconscious or otherwise incapable of consenting and (2) the benefit of treating the patient outweighs any potential harm of the treatment. Under these circumstances, the physician is not required to obtain informed consent before treating, but must do so as soon as it is medically possible [13, 14].

The second exception applies when disclosing medical information would pose a threat to the patient. If, for example, a patient has become so emotionally distraught that he or she would become incapable of making a rational decision, courts generally do not require disclosure [15]. If disclosure is likely to cause psychological harm to the patient, a physician does not have a duty to disclose [16]. However, a physician cannot use the exception to withhold information merely because he or she thinks the information may cause the patient to refuse a specific treatment. In other words, a physician must disclose information that a reasonable person would want to have for decision making, even though that information may cause the patient to refuse treatment that the physician believes is in the patient's best interest [17].

In most states, physicians are not required to disclose specific information about themselves [18]. In *Johnson v. Kokemoor*, however, the court held that a physician may have a legal duty to disclose his or her level of experience with a given technique when a reasonable person would expect to be told this information. The case arose after a patient suffered complications from an aneurysm clip procedure performed by a physician whose lack of experience she was unaware of. The experience of the physician was viewed as a piece of information that was material to an informed decision about the procedure [19].

Given that requirements for informed consent are relatively vague and undefined and the exceptions are few, it is in the physician's best interest to inform patients thoroughly about proposed treatment options, ascertain that they understand their choices, and secure their consent. Doing so will help provide quality patient care and avoid exposure to legal action.

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POLICY FORUM

Vermont's Single-Payer Health Care System: An Interview with Allan Ramsay

Claire K. Ankuda, MD, MPH

In 2011, Vermont legislators approved Act 48, a bill that could lead to the creation of Green Mountain Care, slated to be the country's first single-payer health care system. Allan Ramsay, MD, a family medicine and palliative physician in Vermont, is one of the five members appointed by Governor Peter Shumlin to the Green Mountain Care Board, which is charged with designing a fully integrated, high-quality health care system accessible to all Vermonters.

Claire Ankuda: First, why did you consider applying for this position?

Allan Ramsay: Why, in other words, would a family medicine physician who spent 37 years seeing patients every day and valuing the physician-patient relationship give that up to move into health policy work? This is not easy to answer. I have felt over the past few years that my ability to have a strong physician-patient relationship has been increasingly compromised by the lack of an integrated health care system and by the way health care was financed. I also have been hearing similar stories from my physician colleagues: "it's not about the patient anymore." My clinical and academic career limited my ability to work on important social change. I also wanted to learn more about health care policy.

Giving up patient care has been a difficult process. However this is a unique opportunity to support both primary care and palliative care in a meaningful way.

Claire Ankuda: How did you start thinking about translating Act 48 (Vermont's Health Care Reform bill) into policy in a way that would improve shared decision making?

Allan Ramsay: At the governor's first press conference about the Green Mountain Care Board, I said that if I could do one thing for my primary care colleagues it would be to get rid of the 10-minute visit. You can't do meaningful shared decision making if you are constantly pressured to see more patients in a shorter period of time.

In Vermont, we have an almost $5 billion health care budget, approximately half of which is public money—Medicaid and Medicare. As the cost of health care has grown, the one thing that government can do to control costs is to cut back on reimbursements to the physicians. What does that drive physicians to do? Try to see

more patients. That is one of the problems in a fee-for-service system. The system needs to change to focus on improving quality and value for the patient.

Commercial insurance is the other large financer of health care in this country. The actual percentage of the commercial insurance premium dollar that goes directly to primary care services is very low. By contrast, fully integrated health care systems both in the U.S. and in other developed countries invest much more of each dollar in primary care. They know that is how quality will improve and the costs will be moderated. We don't know what the right percentage of investment per dollar is, but we know we must invest more in primary care in this country.

It all comes down to improved quality at a lower cost and what we value in the health care system. More investment in primary care will lead to improved shared decision making between the patient and clinician.

We must design delivery systems with improved quality and patient experience as the primary goal. I practiced through the years of the failed social experiment called health maintenance organizations (HMOs). HMOs focused only on controlling utilization of services. [Ed. note: In HMOs, physicians were paid a flat amount per patient per year, a system known as "capitation." Capitation created an incentive to keep patient use of services at a minimum.] I never want to see my colleagues called gatekeepers again and expected to make decisions based on controlling the utilization of services. Our delivery system first must focus on improving quality, reducing waste, and avoiding procedures or treatments the patient does not want. Integrating palliative care more effectively for people with life-limiting conditions is a good example of this process.

The most important indicator of quality is the patient experience. But we need to focus on the quality of the clinician experience also. It would be wonderful to walk through the hospital and hear all my colleagues talk about how much more they enjoy the practice of medicine, whatever specialty they are providing. If satisfaction scores are low for health care providers, then we know that patient satisfaction scores will not improve.

Claire Ankuda: Can you give some more specific examples of policies that you believe will improve the way doctors and patients make decisions about health care?

Allan Ramsay: Act 48 establishes the Vermont Blueprint for Health and the patient-centered medical home (PCMH) model as the foundation for the delivery of health care services in Vermont. In 2011, the number of advanced primary care practices, which include the PCMH and community health teams, more than tripled in Vermont. More than half of all Vermonters are now in a PCMH for their medical care. The Blueprint goal is to move away from a strictly fee-for-service system and toward compensation for high-quality, high-value care. In Vermont all insurers, including Medicare and Medicaid, contribute to a monthly per-patient quality-based payment to the clinician in addition to the traditional fee-for-service payment. This

additional payment is designed to achieve the outcomes of improved quality, access, communication, and patient-centered services, rather than just a volume of services. All these factors are essential to improving the way decisions are shared between patients and their doctors.

Claire Ankuda: How do you think your experience as a physician has helped policy makers?

Allan Ramsay: The learning curve has been very steep. I think politicians and policy makers work very hard and endure a lot of criticism, while just trying to do the right thing. Those in the position of changing the health care system don't always see things the way we physicians do. All my fellow Green Mountain Care Board members like to hear stories about patient care—they love doctor stories. When we are discussing a complicated situation about regulations or their impact, telling a story about a patient you've taken care of can put things in perspective.

Transparency and openness are essential in this process. I have met with colleagues throughout the state to be sure they are aware of the health care reform process. In addition all our board deliberations must occur in an open and announced meeting, so that any interested party can listen to the policy discussion. My entire career I have been focused on confidentiality as the foundation of the patient-doctor relationship. It has taken some time for me to adjust, but I am convinced that transparency for the public and those providing health care services is vitally important.

Claire Ankuda: Thanks so much for taking the time to chat. Is there anything else you'd like to add about your time as a policy maker?

Allan Ramsay: One thing I'm very hopeful about is the thoughtfulness of Vermonters. I am a family medicine and a hospice/palliative care physician. Vermonters understand how important both these roles will be in the health care debate. Anyone who has experienced palliative care for a loved one or for themselves knows the value this expertise can bring to the patient experience. During the debate of the Accountable Care Act, I was disgusted by the rhetoric about death panels and limiting care for those near the end of life. As I travel around the state, both my colleagues and others mention to me that improving how we care for those at the end of life is critically important. Vermonters are wise and care about each other. That is so important in getting us to the prize of a high-quality, fully integrated health care system for all.

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MEDICINE AND SOCIETY

The Role of Perception in Quality Communication

Judith A. Hall, PhD

Medical education and theory have embraced the concepts of patient-centered care [1] and relationship-centered care [2] as guiding philosophical principles. According to this view, the clinician and patient are people, not merely the occupants of roles with predetermined rights and obligations, and the patient is appreciated within a broadly defined biopsychosocial realm of experience, expertise, and need. The shift from an emphasis on roles to an emphasis on people means that both participants are considered whole beings with all this implies about personality, values, traits, emotions, and expectations, as well as reciprocal communication and personal commitment.

The shift to the biopsychosocial model also implies that the clinician acknowledge, respect, attend to, and understand much more about the patient than a narrower biomedical model would demand. The implications of the shift to patient-centeredness are profound, for it means that many more processes and outcomes are considered in defining quality of care.

In this essay, I argue that building a good relationship and attaining as much understanding as possible about the patient are basic ethical physician duties. There is now evidence supporting the value of relationship and understanding in promoting desired patient outcomes. In other words, establishing understanding and acknowledging the other's basic humanity are foundational human goals, valuable for their own sakes, but they also further the therapeutic goals of medicine.

Below I present some of the empirical evidence for the latter claim, dividing the discussion into research on the physician's behavior and interpersonal perception skills. This literature, mainly consisting of correlational studies, often leaves open the important question of causality, but the evidence supports the notion that the physician's behavior and perception skills have an impact on the patient.

Although we commonly think and talk about "communication skills" as though they are mainly about *outgoing* communication, the incoming/listening/receiving part may be as important. This latter aspect of physician skill has received much less attention, but we can extrapolate from voluminous research in nonclinical settings that attests to the value of accuracy in perceiving others.

Physicians' Behavior

Reviews conclude that physicians' verbal and nonverbal behaviors correlate with clinical outcomes including patient satisfaction and comprehension of and adherence to treatment and are also indicators of the physician's ability to recognize emotional distress [3-5]. A recent meta-analysis found that the clinician's warmth and listening behaviors were both highly significant predictors of patient satisfaction [5]. Surgeons' malpractice litigation history can be retrospectively predicted from ratings of dominance and unconcern in their voices [6]. With respect to health outcomes in particular, randomized trials to improve the nature of patient-physician communication have had favorable results [7].

Relevant verbal behaviors include empathic statements, statements of reassurance or support, easily understood explanations, positive reinforcement and display of positive emotional reactions through words, and discussion of psychosocial issues and emotions; time spent on health education and longer visit length are also predictors of desired patient outcomes [3-5]. Nonverbal communication also matters, just as it does in everyday life. Nonverbal behaviors that have been linked to desired outcomes (such as patient satisfaction, physicians' recognition of psychosocial problems, and amount of patient participation) include gazing at the patient, having an expressive face, leaning toward the patient, being physically close to the patient, facing the patient directly rather than obliquely, having emotionally positive voice tone, not crossing one's legs and arms, and nodding to the patient (an affirmation as well as a signal to continue talking).

In sum, the verbal and nonverbal behaviors of the physician appear to make a difference in patient outcomes. Although the paths of causality are not known, it is easy to speculate that an approachable, warm, and listening physician will inspire liking, trust, and reciprocity and that these shared psychological states produce favorable effects on recall, adherence, and health outcomes.

Physicians' Perceptive Abilities

A separate, and much smaller, literature addresses the correlates of physicians' abilities in perceiving others accurately. This literature offers tantalizing and encouraging evidence that the ability of physicians to accurately judge others' (mainly emotional) states has predictive value for several different outcomes of the clinical interaction [8].

Studies looking at correlates of physicians' accuracy in judging others typically involve giving the physicians (or other clinicians, including medical students) a test that measures accuracy in judging the emotional meanings of nonverbal cues, such as expressions of the face, body, or voice. The clinicians' accuracy on the test is then used to predict clinically relevant variables.

Studies show that this ability in physicians is correlated with their attention to anxiety and distress in patients, how satisfied their patients are with them, and how well their patients adhere to their appointment schedules [8]. In a study of medical

students, ability of the students to correctly interpret emotional nonverbal cues on a standard test predicted how likeable they were in a subsequently videotaped standard patient interaction, how much compassion they showed to the standard patient, and how engaged the standard patient was in that interaction. In that study, the medical students' scores on the test of decoding emotions through nonverbal cues were associated with their self-reported patient-centered attitudes and with their observed patient-centered behavior in the interaction [9].

A new, unpublished test that I designed specifically for assessing this kind of skill in clinicians in the patient context is currently in the validation process. This test, called the Test of Accurate Perception of Patients' Affect or TAPPA, consists of videoclips of actual patients during routine medical visits. The test-taker chooses from a list of alternative descriptions of what the patient was thinking or feeling during the videoclip, and the correct answer consists of what the patient reported thinking or feeling at that moment during a postvisit review of the videotape.

In a sample of undergraduate nursing students, the more courses with a clinical component the nursing students had taken, the higher they scored on the TAPPA, suggesting that clinical experience fosters accuracy in "reading" patients. In addition, women nursing students scored higher on the TAPPA than did a general sample of women undergraduates at the same institution. In a sample of medical students, after controlling for gender, the TAPPA score was significantly related to the student's belief that psychosocial factors are important in patient care.

The same group of medical students was also assessed during a standardized patient encounter (again, controlling for gender), and those who had scored higher on the TAPPA were rated by trained coders as being more engaged with the patient and often rated as more respectful toward the patient. Thus, the TAPPA results, along with the previously published studies mentioned above, strongly suggest that accuracy in perceiving emotions is an important clinical competency.

Of course, ability to accurately identify emotions is only one kind of perceptiveness. In medical practice, perceptiveness in many matters is likely to be valuable. These include the following:

Interpersonal attitudes: Does the patient like the clinician personally? Does the patient have a negative view of the clinician's race, gender, sexual orientation, and so on? Does the patient trust the clinician?

Personality: Is this a conscientious patient who will take medicine as prescribed? Will the personality of this patient mesh with that of the specialist who is recommended? Does the patient have a hostile personality, meaning the clinician might need to adjust his or her persuasion style? Does the patient have a dependent temperament, meaning the clinician should be careful to keep boundaries clear?

Needs, desires, intentions, expectations: Does the patient want the clinician to talk about his or her emotions? Does the patient want more information?

How much shared decision making is the patient able and willing to engage in?

Deception: Does the patient really have safe sex as claimed? Is the patient telling the truth about bruises? Is the patient lying about pain in order to get painkilling medications?

Physical states: How extreme is the ill patient's pain? Is she abnormally fatigued? Does the patient's agitation suggest he might be on drugs?

Cognitive states: Is the patient confused by the clinician's vocabulary? Does he display signs of dementia?

Research to investigate accuracy in perceiving these aspects or attributes remains to be done.

Conclusions

This brief review gives evidence that communication style and ability to perceive others' emotional states are components of quality care and represent core ethical goals of medical practice. The notion that these are optional "bedside manners" is, thank goodness, dead forever.

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Informed Consent for Off-Label Use of Prescription Medications

Zain Mithani, MD

In the 1960s, British pharmacologist John Vane made a very interesting discovery in his laboratory at the University of London. Vane found that aspirin, a drug that for many years was used primarily to relieve minor pain and fevers, could disrupt a pathway needed for platelet aggregation. Further studies in the 1980s showed that this effect could be used for the prevention of heart attacks and stroke. Despite the evidence, the Food and Drug Administration (FDA) prevented manufacturers from advertising this information until more convincing clinical trials of aspirin's anticoagulant action had been completed. Doctors, in the meantime, were allowed to prescribe aspirin for this purported use. In fact, it was not until 1998 that the FDA finally approved aspirin for the prevention of cardiovascular events [1].

Should manufacturers be allowed to advertise off-label uses of their drugs for which they have credible research? Would this use of aspirin have prevented the deaths of patients who would have asked to be put on it had they seen it advertised as an anticoagulant? Conversely, should physicians be allowed to prescribe drugs that a governing body like the FDA has not determined to be unequivocally safe for use by the general public? This article is in favor of transparency and examines what reasonable people would want to know about the drugs they are being prescribed.

Once a drug has been approved by the FDA for one purpose, a physician can prescribe that drug for any purpose. The practice of prescribing a drug for a purpose other than that for which it is approved is known as "off-label" use [2]. Off-label use is legal and does not necessarily mean that the drug is being used inappropriately [2]. In fact, many physicians prescribe a drug off label because they believe it is the best treatment for a specific condition even though it has not yet been formally tested for use in that condition [2, 3]. Off-label use becomes an ethical, not a legal, issue when the principle of informed consent is introduced.

The concept of informed consent as it is currently understood arose in response to the many medical research abuses of the middle half of the twentieth century—from the mid-1930s through the mid-1970s—in Nazi Germany and the United States. Simply put, informed consent demands that patients give their consent to any treatment or research protocol that a clinician proposes. The "informed" part of the term forces us to ask: how much information must patients receive in order to be able to give "informed" consent?

Given the status that the principle of informed consent enjoys in U.S. medicine today, it should seem strange that physicians commonly prescribe drugs without informing patients that these drugs have not been approved for the use in question. Most patients believe, rightly, that all drugs prescribed by physicians have been approved by the FDA [4]. What most patients do not know or question is whether a given drug has received FDA approval for a specific purpose. It is interesting to note that, despite being such a controversial issue, relatively little has been published about informed consent for off-label use.

Arguments for Requiring Consent for Off-Label Use

Informed consent is a principle that is observed to ensure that patient autonomy is preserved, requiring that competent patients are made aware of and understand enough about the intended benefits and possible risks of proposed treatment to make an informed decision [5]. This consent can be implied by the patient's lack of protest, and, in the case of many routine medical interventions, it is. The FDA requires explicit written consent for drugs being used experimentally or as a part of research, but no explicit consent is required for any off-label drug use if it can be argued that, like any other treatment, the drug is being used in the patient's best interests [6].

Nearly all physicians prescribe drugs for off-label purposes without informing their patients that the drug has not been approved for the purpose they intend [4]. Is it acceptable for a physician to neglect to tell patients of a drug's off-label status? It could be argued that the physician who withholds that information is violating the ethical duty to secure the patient's informed consent [4].

FDA panels have found that some off-label uses can be dangerous. The example of fenfluramine emphasizes this point. Eighteen million prescriptions for the off-label use of fenfluramine as a weight-loss drug were written before it was concluded that it had caused heart-valve damage in thousands of people [4].

A recent survey seemed to increase safety concerns [7]. The survey looked at 150 million prescriptions for off-label use in the United States and found that 73 percent had little to no scientific backing. The study concluded that "off-label medication use is common in outpatient care, and most occurs without scientific support" [7].

Doctors are legally bound to inform patients of risks. The fact the there is a lack of research for off-label use should be considered a risk to the patient. Hence, physicians should follow legal standards that require them "to obtain informed consent from a person before performing a test or stating a treatment—particularly a treatment that involves some uncertainty" [4]. It should follow then that physicians be required to inform patients of off-label use, but this does not seem to be the case.

Doctors are often encouraged to practice an approach known as shared decision making, a model that many consider to be the best guide for the patient-physician relationship. In short, shared decision making requires that both the physician and

patient share information and work together to decide on a treatment plan [4]. Clearly, withholding the intent to prescribe a drug for off-label use fails to honor this approach to the relationship.

To investigate a new use of a drug, a manufacturer has to apply for the investigational new drug (IND) process, which requires that the drug undergo monitored clinical trials to prove its safety in off-label uses. In the meantime, the drug can be prescribed off-label if explicit consent is given by the patients prescribed it [8]. If the drug proves to be safe for a new use, the manufacturer could then submit a new drug application to the FDA, after the approval of which the drug can be used without explicit informed consent for its new use. It is notable that consent is required of participants in a drug trial because the drug's effects have yet to be shown, but consent is not required for a drug prescribed in a clinical setting for a purpose that has not been fully studied.

It could be argued that, given the documented lack of scientific support, off-label drug use should be considered experimental or investigational; the use supports a theoretical assumption on the physician's part. If off-label use were classified as experimental, physicians would be required to obtain explicit consent from patients, most commonly in the form of written consent.

The Argument for Not Requiring Consent for Off-Label Use

One may wonder why, even though the ethical and legal principles of informed consent and shared decision making are not being upheld, off-label use has become so prevalent in the daily practice of medicine. The lack of scientific support for most drug use of this type should serve to heighten these concerns. Some contend, however, that there are logical reasons not to inform patients of a drug's off-label status and instances in which off-label use is actually beneficial.

The most commonly used defense of off-label drug use is that acquiring FDA approval for all uses is not economically feasible. This is especially true in pediatric care, in which three-fourths of prescription drugs are used off label [2, 6]. It is not cost-effective for pharmaceutical companies to get drugs reapproved for children or for other uses [6]. Once a drug is determined to be safe and effective for one use, the pharmaceutical industry relies on the off-label market to expand its sales potential.

Some have contended that the risks involved in using drugs off label are no different than the risk of any medical intervention [2, 8]. Any intervention requires, at the least, an implied consent. Proponents of this argument claim that the "mere fact of off-label use, however, is a matter solely of FDA regulatory status and cannot logically be considered a medical risk of a drug or medical device" [8], suggesting that off-label status is irrelevant to the actual medical risks posed. It has also been argued that a lack of FDA approval does not preclude the drug's being effective or being standard care [3].

The argument is that informing patients of the off-label status would "confound patient decision making by diverting attention to medically irrelevant information" [5]. Proponents of the position argue further that forcing physicians to "learn and discuss legal/administrative (rather than medical) facts [could be] potentially to their detriment and to the detriment of their patients" [8].

It may alarm some that "current practice does not require or even suggest that doctors disclose any of these facts to their patients" [4]. This practice has been amplified by court decisions on the matter. The case of *Alvarez v. Smith* is a good example of courts' take on the use of a medical device off label. This case was a class-action suit by patients whose surgeons had implanted in their spines screws that had been approved for use in long bones (i.e., arms and legs) only. Many surgeons used the screws off label, and more than 2,000 patients claimed that they had suffered postoperative injuries as a result.

The courts, which have a history of being lenient on off-label use, relied upon past precedent to decide the case in the physicians' favor [9]. In an earlier ruling, the court had determined that "while patients might have some assurance that uses actually appearing on labeling are safe and effective, they cannot imply from a label's silence that a particular use recommended by their physician is unsafe, risky, novel, or untried" [5].

Another angle that proponents of off-label drug use take is pointing out that FDA approval is not a guarantee of safety [9]—despite FDA approval, drugs like Vioxx have had serious health implications for *on-label* use. This supports the argument that specifically discussing the off-label status of a drug may wrongly imply that "on-label" means "guaranteed safe," and could distract patients and clinicians from the real conversation that needs to occur about risks. To complicate matters, different jurisdictions within the United States have different concepts of what constitutes informed consent [10]. Without a clear stance taken by the legal establishment, the medical establishment is less able to set up a model of best practice on this issue and has less incentive to do so.

Although it would be a stretch to do so, physicians might invoke "therapeutic privilege" to excuse them from the legal principle of informed consent [10]. Therapeutic privilege allows physicians to circumvent informed consent when "full disclosure would be detrimental to a patient's total care and best interests" [4]. A physician who wished to use therapeutic privilege to justify not informing a patient of off-label drug use would have to prove that telling the patient would be detrimental to the patient's health [4]. A patient with end-stage disease, perhaps, might refuse a treatment upon learning that it was not approved by the FDA, and the physician might judge that refusal of the drug would have serious implications for the patient.

Therapeutic privilege, as one can imagine, is a hotly debated issue. Many argue that it too often allows physicians to set aside legal requirements and ethical principles in

order to provide the treatments that they see as best, but that are not necessarily what their patients want. The American Medical Association *Code of Medical Ethics* takes a much narrower stance, stating that "physicians may withhold information about a patient's diagnosis or treatment when disclosing it would pose a serious psychological threat, so serious a threat as to be medically contraindicated" [11]. Clearly, this would limit the number of cases that could justify the use of therapeutic privilege.

Whether or not to inform patients of off-label drug use has been the subject of heated debate for a long time, with convincing arguments made on both sides of the issue and no consensus reached. What must be said is that physicians should follow evidence-based standards of care constructed from comprehensive studies looking at health outcomes, patient satisfaction, and the feasibility of the proposed methods.

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OP-ED

Selective Paternalism

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The increase in diagnostic and therapeutic options over the last half century has created more medical decision making situations. Yet the process of medical decision making remains nebulous. Many decisions (e.g., ordering routine blood tests) are made unilaterally by physicians, while others (e.g., elective surgical procedures, medication adherence) involve more patient choice. In many cases, decisions may not be straightforward, and the choices of patients do not always align with the advice of physicians. Practice standards that guide decision making have shifted greatly in recent decades from a paternalistic model to one based on respect for patient autonomy and, more recently, to shared decision making (SDM) [1-3].

These models, however, focus more on who makes the decision than on how the decision is made. Therefore, our aim is to identify elemental characteristics necessary for decision making, establish how they affect the information exchange between physician and patient, and provide an ethical framework for the SDM process.

Shared decision making is an active dialogue between physician and patient with the goal of arriving at mutual understanding and agreement on a treatment plan [1, 3]. With the shift in decision making roles, SDM has been interpreted in various ways that describe rigid authority roles (for either patient or physician) that do not accord well with the process of decision making [4]. A recently published shared decision making continuum proposes a shifting balance between physician expertise (paternalism) and respect for patient autonomy [5]. This framework depicts varying degrees of patient and physician authority with regard to the decision-making process, rendering SDM increasingly adaptable to clinical practice.

Studies of shared decision making link increased patient involvement to improved treatment adherence, disease coping, and quality of life, whereas lack of patient involvement correlates with lower adherence to treatment, patient satisfaction, and health outcomes [6, 7]. The advantages of SDM are clear: maximizing the likelihood that both patient and physician will be respected, satisfied, and invested in the outcome.

Limits to Shared Decision Making

These advantages may only prove successful under ideal circumstances [8, 9], however, and be less effective with patients who are in denial or lack health literacy and do not understand disease processes and treatment implications. Physicians may

view requests from these patients as impractical, unjust, or even harmful from a professional point of view and may feel they are being asked to give inappropriate or futile care [10]. Finally, SDM is predicated on the presumption that an agreement will be reached between patient and physician, failing to account for the inevitable occurrence of unresolved disagreements [9]. Under such circumstances, SDM breaks down.

In contemporary medical ethics, when a shared decision cannot be reached, respect for patient autonomy is often considered the most important principle to follow, while paternalism has been relegated to a nearly historical perverse concept [11, 12]. Yet, the practice of physician-driven decision making is far more common than many physicians recognize or may care to admit. There are many situations, neither emergent nor life-threatening, in which physicians diagnose or treat patients without their knowledge or consent [8]. The subtleties of medical decision making are complex, and standards delineating a balance between patient autonomy and medical paternalism remain undefined. Efforts to generate decision-making parameters are often undermined by the unique nature of patient-specific values and preferences. This variability leaves physicians to interpret situation-dependent conditions without clear guidelines. To best describe the practice of situational decision making by physicians, we propose the concept *selective paternalism*.

Broadly defined, paternalism is an action performed with the intent of promoting another's good but occurring against the other's will or without the other's consent [13]. In medicine, it refers to acts of authority by the physician in directing care and distribution of resources to patients. Medicine is a practice, not a mere formulary of facts; the expertise of the physician developed through years of education, apprenticeship, and experience cannot be fully imparted to the patient, hence, knowledge-based value judgments are essential to good medical care, and the physician must not be a passive participant [12, 14, 15]. This means that paternalism is inherent in the physician role and, thus, in the decision-making process.

Paternalism—choosing a course of action in the patient's best interest but without the patient's consent—serves as an integral value in ethical decision making, both as a balance to other values and as an ethical obligation to neither withhold guidance nor abdicate professional responsibility to patients [12, 16, 17].

Understanding Selective Paternalism

Selective paternalism—the use of paternalism when, for any number of reasons, shared decision making breaks down—is commonplace in clinical practice in different degrees and various scenarios [3, 7, 8, 18], and must be recognized, discussed, and embraced as necessary for optimal patient care.

Paternalism does not serve as an endpoint or solution but as one of many integral values in the decision-making process. Just as the primary value of a moral rule is to alert us to the presence of a moral problem, thereby opening the door to potential resolution or alternatives to the dilemma, so selective paternalism should effectively

promote awareness, productive dialogue, and prevention of error in decision-making situations [16].

Although respect for patient autonomy is imperative and there are benefits to pursuing shared decision making, there are scenarios in which SDM is impractical or even impossible. Medical decisions are often emotion-laden and induce distress, confusion, and conflict among patients and families, which can impair their desire and ability to participate in decision making [6].

Consider an example in which a 60-year-old man removes his nasogastric tube, telemetry leads, pulse oximeter, and supplemental oxygen at 2:00 AM immediately following abdominal surgery. The intern is called and sees the patient at the bedside. The patient requests that the Foley catheter and intravenous line be taken out; he is uncomfortable and does not want to be in the hospital any longer. Nurses have attempted to calm the patient for several hours, but he has become more agitated because his requests are not being followed. When examined by the intern, the patient is alert, oriented, and judged to have decision-making capacity. He (1) understands the treatment goals, (2) appreciates the significance of his decisions, (3) displays reasoning for his decisions, and (4) appropriately expresses choices that fall within his system of values [19]. The nurses request chemical or mechanical restraints for the patient.

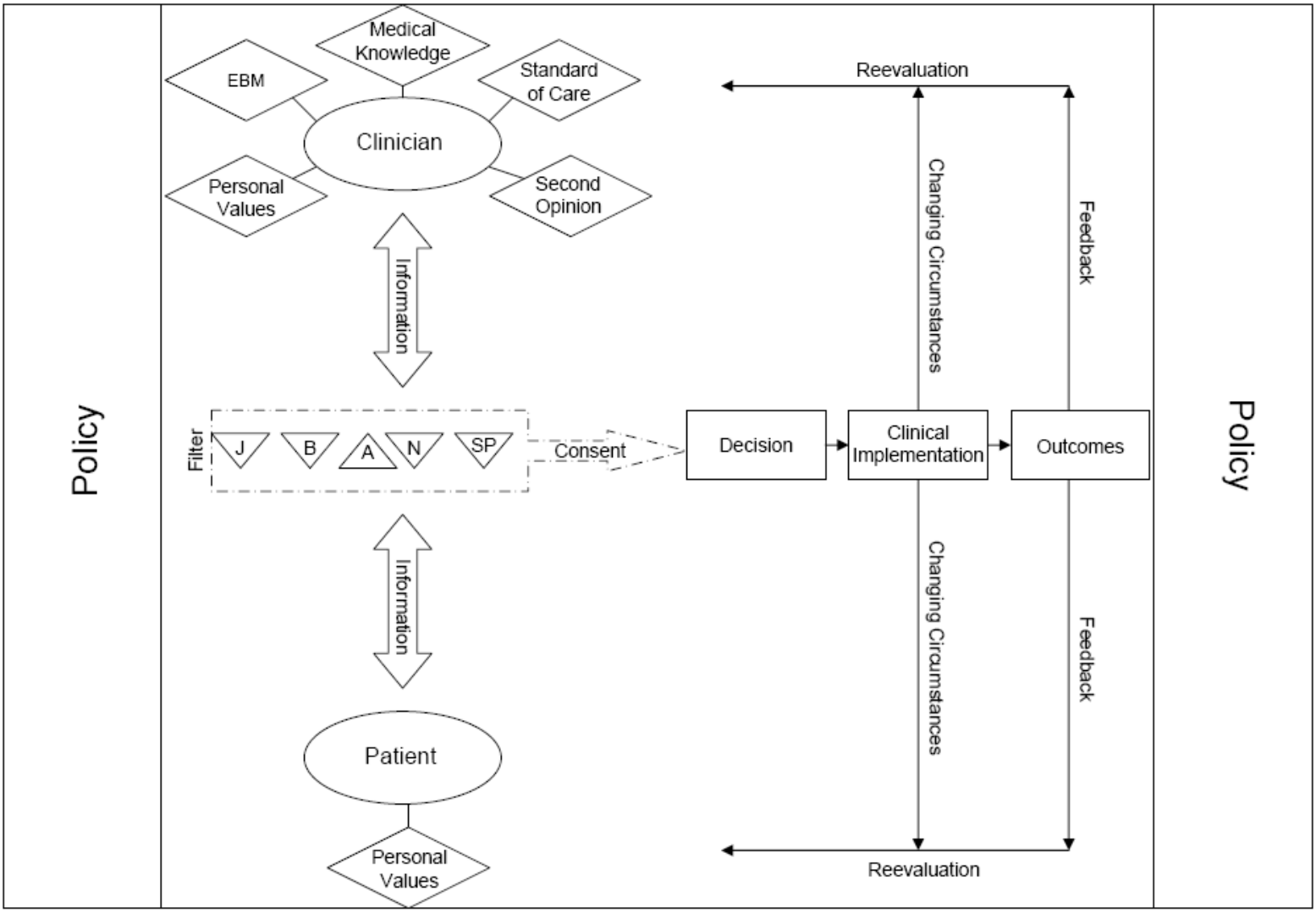
Or suppose that a 20-year-old woman suffers devastating central neurological injuries from a motor vehicle accident and is left ventilator-dependent with poor chances of recovery. Her care team advises that tracheostomy and percutaneous gastrostomy be performed or that life support be withdrawn. Her mother, the lone surrogate decision maker, is unable and ultimately unwilling to decide on a plan of care; she does not consent to aggressive intervention or withdrawal of care. Multiple family meetings are unproductive at identifying a plan of care.

Physicians should respond to such situations with a more paternalistic approach, bearing the professional responsibility to act in the patient's best interest and justly appropriate medical resources [20]. Ideally, patient autonomy is respected, not invoked as an excuse for abdication of professional responsibility or justification of unjust, futile use of resources [21, 22].

There are critical implications to the loss of physician-driven decision making in medicine. In many fields (e.g., law, education, economics), it is generally accepted that decisions are best made by experts. Within their respective fields, experts are charged with understanding the nuances required for best practice of the profession. Physicians are obligated to ensure quality and value in health care through education, expertise, and ethical practice patterns. Despite the common political opinion, medicine is not a simple consumer-producer market, and physicians cannot be forced into a fully patient-autonomous system. Furthermore, a default overemphasis on autonomy hinders the upholding of other central values in medical ethics: respect for autonomy must be balanced with nonmaleficence, beneficence, justice, and the

paternalistic obligation to uphold standards of care [14]. Utilizing paternalism selectively in decision making is not only necessary but obligatory [16, 17].

Defining specific limits of physician or patient authority that would be applicable to all situations is an impossible task, but, since selective paternalism is commonplace and essential in clinical practice, a model of the process is both pragmatic and necessary. We have created a framework that identifies necessary elements of ethical decision making, based on that of Mulley and Sepucha, most recently revised in 2009 [6].



Key: **J**: justice; **B**: beneficence; **A**: autonomy; **N**: nonmaleficence; **SP**: selective paternalism; **EBM**: evidence-based medicine

Figure 1. Shared decision making model (Modified from Sepucha and Mulley [6]).

The original model underemphasized *how* one arrives at a decision, and, while it identifies the necessary participants, separates them from the decision. Our SDM framework focuses on how the decision process occurs by identifying elements that each participant represents and how those elements should be applied using a set of mandatory ethical value "filters" in order to reach consent [18]. This, in turn, can lead to the formation of a shared decision.

Policy creates the system in which clinicians and patients interact. Each participant, physician and patient, necessarily has an active role in shared decision making, introducing a variety of elements into the system, information that is used to determine consent and decision. Information flow between physician and patient with direct implications for decision making should be guided by applying values that promote ethical decision making and prevent imbalance among the values that could lead to abuse. A successful flow of information produces informed consent, from which a decision is made and subsequently enacted in clinical practice, with outcomes to follow that, in turn, render feedback to the participants.

The values represented as "filters" should be applied in every decision-making scenario. Failure to apply these values in decision making leads to a failure of communication, arresting shared decision making, and decisions made without these values can have dire consequences.

Conclusion

As physicians, most of us pride ourselves on respecting patient autonomy and the involvement of patients in the decision-making process, but we overlook the frequent occurrences of selective paternalism and often fail to use it appropriately or consistently. Instead, as physicians we should be both cautious and conscientious about our paternalistic decision making. We should acknowledge how we make decisions, thoughtfully reconsider those that may allow for an SDM process, and, at all times, take responsibility for ensuring the highest standards of ethical practice are enacted and embrace those decisions that are in patients' best interest.

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