

Forum

Risk Management Foundation of the Harvard Medical Institutions



Ethics and Risk Management Concerns

Issue Editor: Denise Bisailon

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Commentary: It's Rarely a Simple Decision

by
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Ethical decisions permeate medical care. What do you ask patients, what do you tell them? Do you aggressively treat a dying patient's infection? Do you prescribe an unnecessary drug for patient appeasement? Do you tell a patient's family information that might protect them, but violates that patient's confidentiality?

Rarely are such decisions black and white. In fact, they are often so subtle or embedded in your daily practice routine that they are made without contemplation. Certainly they are influenced by the individual personalities, histories, and situations. It may be only when the quality or outcome of care is challenged via allegations of malpractice that the ethical aspect of decisions come to light.

To help you consider these issues before you are confronted by them in the form of a complaint, *Forum* has asked experts in several realms of modern medical care to discuss how they perceive the ethical questions that arise in their environments.

While the issue of informed consent is rarely the primary reason a patient takes action against his or her provider, diligent attention to the consent process can enhance patient care and reduce the chances of unexpected outcomes...and disillusioned patients. Some stubborn myths surrounding the nuts and bolts of informed consent are dispelled by **Mark Kuczewski, Ph.D.**, and **Alan Meisel, J.D.**, in their article on *Page 2*.

In a setting where the outcome is not always so unexpected, a hospital intensive care unit (ICU) grapples with issues such as when to suspend or withhold care can easily become ethical debates. **Dr. Robert Truog** (*Page 4*) explains some of the work undertaken by several Harvard-affiliated ICUs to anticipate, address, and resolve questions of futility and other end-of-life decisions.

Regardless of the care setting, the cultural diversity of patients and providers has been widely recognized as a factor related to inadequate communication of medical information. On *Page 6*, **Dr. Eric Krakauer** discusses some of the historical factors that may have led to miscommunication and some tactics for improving cross-cultural care.

Much more recently, the subject of genetic testing has been the focus of ethical debate. When to test, who to tell, and what to do with information you might not have even been looking for is the subject of **Dorothy Wertz's** article on *Page 8*.

Another element of medical care where the question is shifting from "if" to "when" is the rationing of services for patients. In his article on *Page 10*, **Dr. Peter Ubel** demonstrates how the broad application of economic factors is impacting the bedside decisions clinicians must make.

Both longstanding and emerging ethical issues are often difficult to grasp until you're faced with a real decision about a real patient. As illustrated by the **Closed Case Abstract** on *Page 12*, even fairly familiar situations such as blood transfusions for Jehovah's Witnesses, can break down when other complicating factors are introduced. As demonstrated by this case, however, a defensible decision-making process can support challenges to the decision that was made.

By presenting this array of ethical issues, and perhaps engendering further study or discussion, *Forum* hopes to leave you better prepared for such decisions. ■

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Demystifying Myths About Informed Consent

The concept of informed consent often engenders a degree of mythology. It was conceived as the ultimate protection from liability and the best way to manage risk. In reality, achieving that protection requires treating informed consent according to the *spirit* of the law. When informed consent is implemented according to the *letter* of the law alone, several of the myths about it gain currency. Falling prey to these myths may result in clinical conflict and litigation.

Myth #1 “A Signed Consent Form is Informed Consent”

Nothing could be further from the truth, as many courts have pointed out to physicians who were only too willing to believe this myth. Consent forms are used as a matter of routine in both treatment and research settings because many hospital administrators, physicians, and their attorneys see these forms as providing protection against liability, despite the fact that they provide little protection.

Consent forms can have some value. They create an inference that the patient at least had an opportunity to read the information on it. If the information presented in the consent form is adequate for a patient to make a decision, it will probably be helpful in the defense of a malpractice lawsuit.

Contemporary forms are often optimistically referred to as “informed consent forms”—as if wishing would make it so. Under this guise, they provide a false sense of security to physicians and hospital administrators who are led to believe that a signed consent form constitutes informed consent. As a result, more progressive institutions are often doing away with standardized consent forms and require that physicians document the content of their conversations with patients in their patient’s medical records. This may facilitate a more intimate and patient-centered consent process that does not rely on the jargon and out-of-context information of standardized forms.

Myth #2 “Informed Consent is a Miranda Warning”

Certainly as symbolized by consent forms, informed consent is often no more than a medical *Miranda* warning. Just as police are required to inform criminal suspects of their rights, some physicians believe that informed consent has been obtained if they warn patients of the risks of treatment.

Certainly patients should be told about the risks of treatment, but the approach to informed consent that we advocate makes this less important. Rather than focusing on risks, the focus needs to be on therapeutic options. For example, patients with

ulcers need to know about medical treatment and surgical treatment. Patients with breast cancer need to know about different kinds and combinations of surgery, radiation, and chemotherapy. And all patients always need to know that one of their options is to refrain from treatment altogether.

Knowledge of one’s options alone, however, is not meaningful unless one also knows the range of consequences of choosing each option. The risk of treatment is one facet of information, but others, such as information about the likely outcomes, including mortality, morbidity, and functioning, also need to be discussed.

Myth #3 “Physicians Have to Operate a Medical Cafeteria”

A myth that contradicts the previous one, yet is some-times held simultaneously with it, is that physicians must set out all of the therapeutic options before patients and let patients choose. The law clearly does not require this.

When this myth is at work, the physician’s role as medical advisor is in peril. Patients usually want more than information. They also want advice. That does not mean they are going to do what their physician would do, nor does it mean that they should have just let the physician decide from the outset. What it means is that part of the informed consent process is human interaction.

Informed consent conversations should help patients get information, ask questions, give information, say “I want to think about it” or “I’ve thought about it and I can’t decide. What do you think I should do?” Thus viewed, informed consent is a process of *shared* or *collaborative* decision making.²

Another way of looking at the process is that it must mix together treatment goals and particular treatments. Most of the confusion surrounding the cafeteria approach to informed consent assumes that patients wish to micromanage their care. This is rarely the case.³ However, patients are entitled to know the goals of therapeutic options and when that goal has changed.

Too often, patients are not really sure what the treatment is ultimately meant to do. Similarly, when new treatments are introduced and discussed, it is not always clear to the patient that the old goal is no longer realistic—e.g., cure is no longer possible—and that this new treatment is directed at a different goal such as minimizing disability or relieving pain. Patients are not experts at treatments, physicians are; but patients’ preferences are central to the choice

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This article is adapted with permission from the *Archives of Internal Medicine*.¹

of treatment goals. Thus, in selecting and revising treatment goals, physicians and patients need to form a partnership.⁴

Myth #4 “Patients Must Be Told Everything”

Actually, the law requires only that patients be given a *reasonable* amount of information. In about half the states, what is “reasonable” is measured by customary professional practice: patients must be given the information that a reasonable *physician* would disclose. In the remaining states, reasonableness is measured by a so-called legal standard: patients must be given the amount and kind of information that a reasonable *patient* would find material to making a decision about treatment.

Because those rules are vague, physicians lack specific guidance about how to comply. Some feel driven to disclose everything, which is unnecessary. Once a physician and patient have explored all the relatively realistic goals of treatment, the number of therapeutic options and information about those options frequently become relatively minor issues.

Myth #5 “Patients Can’t Understand Complex Information”

Some physicians believe that providing consent information to patients frightens them, that patients quickly forget the information, and that patients lack sufficient technical knowledge to participate in medical decision making.⁵

The first error in this reasoning is the equation of recall with understanding. While someone who cannot retain information might not be said to understand it, people often make reasonable decisions but cannot later recall the premise or process that supported their reasoning. Nevertheless, they might well have understood it at the time and would likely make the same choice again.

The second error is the assumption that patients must understand information in the same way and detail as the physician. A patient who is totally bereft of understanding lacks decision-making capacity and would be considered legally incompetent. But putting an odd gloss on information, or not having a completely accurate understanding of the information does not disqualify that patient as a decision maker.^{6,8} Patients merely need to be able to understand the potential risks and benefits of their options.

Informed consent steers a course between extremes. One extreme assumes that a patient just cannot understand medical information, and clinicians should abandon informed consent. At the other end of the spectrum resides the extreme rights-oriented view that a patient’s treatment choices should not be challenged. The middle path is where the patient’s choices make sense in terms of his or her values and way of making sense of the world.

Myth #6 “Patients Must Participate in Decisions”

Some patients choose not to participate in decision making at all or may wish to participate on a reduced basis. Withholding information from patients when they request that it not be given respects their autonomy as much as providing information to patients who want it. Respecting the wishes of patients who opt out of decision making is another way of fostering self-determination.

Withholding information from patients at their request is a legally recognized exception to informed consent referred to as “waiver.”⁹ The waiver exception parallels the two distinct but related rights that informed consent embodies: the right to be given information, and the right to decide. Patients waiving their right to decide do not automatically waive their right to information.

Clinicians may have good reasons to continue to provide information to such patients. The fact that a patient does not want to make a particular treatment decision does not mean that he will not wish to participate in the future. Furthermore, patients also need information to facilitate compliance with treatment decisions. They deserve information about their treatment as a sign of respect and so that they can be prepared for what is to happen to them.

Conclusion

Viewed as a process of shared decision making, some of the seeming absurdities associated with informed consent disappear and it becomes a useful tool in making the patient a partner in managing risk. Have a conversation; have several; remember that this is a process. In this process, you will gradually come to know your patient’s decision-making style. Furthermore, don’t press patients to decide quickly; don’t make them think you don’t have time for them. Because if you do—regardless of how much information they’re given—they’re going to be angry, and another name for an angry patient is “plaintiff.” ■

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Addressing Ethical Conflicts in the ICU

In early 1995, representatives from the medical and nursing leadership of the Harvard-affiliated ICUs met to discuss ethical issues of mutual concern. One topic completely dominated the discussion: demands of families for continued aggressive treatment of loved ones against the advice of the ICU clinicians. The subject was not new; indeed the concept of medical “futility” had become something of a buzzword in the medical literature since it had first been introduced in the late 1980s.^{1,2} At least two of the ICUs had already encountered high-profile ethical and legal cases that revolved around this concept.^{3,4}

At that time, many hospitals were trying to develop definitions of futility, based upon standardized assessments regarding the probability of success or the quality of the outcome.⁵ The Harvard clinicians believed, however, that these highly generalized approaches to determining futility were unlikely to be very helpful in most clinical situations. Just as approaches toward managing specific diseases need to be tailored to the particular circumstances of the individual, so do approaches toward managing conflict need to be resolved with regard to the particular and unique concerns of the patient and family.

A Breakdown in Trust

As discussion continued, two other factors emerged as relevant to the frustration of the ICU clinicians over demands for “futile” treatments. First was the recognition that most of these conflicts arise amidst a breakdown in trust between the patient, the family, and the clinicians. This lack of trust may have roots that are cultural, religious, or historical, or it may develop when these relationships simply “get off on the wrong foot.”⁶ Whatever the cause, in these cases the clinicians’ recommendations to refrain from continued aggressive treatment are often seen by the patient and family as self-serving recommendations, motivated by the clinicians’ desires to save money, reduce their work load, or simply to get rid of a difficult case. If better communication early in the ICU course could be effective at preventing this breakdown in trust, then perhaps these conflicts over futile treatment could be avoided.

The second motivating factor these ICU clinicians recognized was the lack of any coherent treatment alternatives. In other words, the ICU environment has often operated under the assumption that there is no alternative to an all-out effort to achieve cure.

Until recently, this philosophy has been deeply rooted in the collective psyches of intensive care physicians and nurses. Whenever patients or families expressed ambivalence about wanting to “do everything,” the patient was no longer considered appropriate for intensive care. Undoubtedly, this (somewhat) implicit assumption was also perceived by patients and families, who recognized that if they stopped insisting upon aggressive and potentially curative treatment they would be rejected and abandoned by the ICU team.

Fortunately, this old model of ICU care is slowly converting to the philosophy that success is not defined entirely by low mortality rates. While many ICU patients can be effectively transferred to other environments to die (home, hospice, or hospital ward), others need to stay in the ICU until their death, usually because they are dependent upon life-support systems that can only be safely managed in the ICU setting. For these patients, ICUs need to develop strategies for providing effective palliation as well as cures. In addition to counting survivors, success can be defined in terms of the number of “good deaths” that occur.

A Program for Reducing Conflict

In 1997, the Harvard-affiliated ICUs organized a two-day workshop to further explore and build upon the three themes that had been identified: first, to design and implement a program for improving communication and reducing conflict between patients, families, and clinicians; second, to develop explicit guidelines for providing palliative care in the ICU; and third, to develop a workable approach toward determining when treatments are futile.

Goal #1: Care Improvement for the Critically Ill

The first goal is being realized through an initiative known as the CICI project (Care Improvement for the Critically Ill), sponsored by Risk Management Foundation. In November 1998, eight Harvard-affiliated ICUs began four months of intensive data collection. This combination of interview and survey data will provide insight into the experiences of patients and families around their ICU admissions. The data will also be correlated with similar information obtained from the physicians and nurses caring for these patients. Preliminary analysis indicates that, while patients and families are generally quite satisfied with the care they are receiving in these units, both physicians and nurses underestimate the degree of pain and suffering that the patients and families are experiencing.

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After this baseline data collection, all eight ICUs were charged with developing an intervention designed to improve the experiences of patients and families. Based upon preliminary unpublished work, all of the ICUs chose to adopt a four-part intervention process.

First, the clinical team identifies families at high risk for conflict using four criteria: expressed anger or conflict, prolonged length of stay in the ICU, the absence of an identified surrogate decision maker, or an ICU admission triggered by an iatrogenic event.

Second, the unit social worker or another clinician skilled in interpersonal communication performs a structured interview with the patient or family, focusing upon four domains: information giving and understanding, communication, conflict, and psychosocial support.

Third, the social worker or other clinician meets with the clinical team on rounds the following morning and provides feedback to the team about the findings from the structured interview.

Fourth, the clinical team develops a list of recommendations that they will pursue, based upon the information received. These recommendations may range from scheduling a team meeting, to obtaining a second opinion for the patient, to obtaining formal input from the hospital ethics committee.

Beginning in June 1999, each of the participating ICUs implemented some closely related version of this intervention. Once again, research assistants embarked on an intensive four-month period of data collection to determine whether the experiences of patients and families have improved from baseline.

Goal #2: Developing Palliative Care Guidelines

The second goal identified at the 1997 workshop was to develop guidelines for providing palliative care in the ICU. More specifically, the workshop participants observed that there is a notable lack of information in the medical literature on the “nuts and bolts” of withdrawing life-sustaining treatments.

This event, usually associated with the imminent death of the patient, often will define for surviving family members whether or not their loved one had a “good death.” Despite its importance, little is known about the preferred sequence for withdrawing life-sustaining treatments, the best medications for providing pain relief and sedation, or the most effective protocols for escalating the dosages of these medications in response to increasing pain or tolerance. Several participants from the 1997 workshop are collaborating with national organizations like the Society of Critical Care Medicine and the American Thoracic Society, with the intention of developing clear and explicit guidelines on these issues within the next year.

Goal #3: A Useful Approach to Determining Futility

The final goal articulated at the 1997 workshop was to return to where the dialogue began, and develop a theoretically sound yet clinically useful approach to determining medical futility. As noted above, futility has proven to be notoriously difficult to define. In this respect, U.S. Supreme Court Justice Potter Stewart’s comments about pornography may apply equally well to futility: “It may be impossible to define, but we know it when we see it.”⁷

As such, at least one medical community,⁸ as well as the American Medical Association,⁹ have endorsed a procedural (as opposed to definitional) approach toward determining futility in specific cases. In other words, these groups have advocated a case-by-case approach to determining when cases are futile, using multidisciplinary groups like ethics committees to adjudicate between the demands of the patient and family and the recommendations of the caregivers.

While not foreclosing any legal options for the patient or family, the hope is that such an institutional deliberative process will be able to engage the family in collaborative decision making and avoid the need for asking the courts to decide. Thus far, both Boston’s Children’s Hospital and the Mount Auburn Hospital, in Cambridge, have adopted procedural-based futility policies; Massachusetts General Hospital is currently developing a similar approach.

Over the last five years, the ethical dilemmas encountered by ICU clinicians have provided a forum for these physicians and nurses to collaborate around shared concerns. In turn, these have led to initiatives that we hope will result in significant improvements in the care that we are providing to the most critically ill members of the hospitalized population. ■

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Cultural Difference, Trust, and Optimum Care for Minority Patients

Mr. B. was a 60-year-old, working-class, African-American resident of an inner-city nursing home with a history of advanced colon cancer metastatic to the liver, profound dementia, and diabetes mellitus. He presented to the emergency department (ED) in septic shock with pyuria and multi-lobar pneumonia. The European-American resident and attending physician in the ED suggested to the family that the patient be given comfort care only and protected from cardiopulmonary resuscitation. The family insisted that all life-sustaining treatments be used. When the ED physicians invoked "medical futility" and refused to intubate Mr. B. for respiratory failure, family members became very angry.^{1,2}

When patients, families, and physicians deliberate about life-sustaining treatment, conflict can arise if participants in the discussion fail to appreciate subtleties of the medical situation or of personal values of other participants. Specifically, a participant may be motivated by guilt, denial, inability to accept death, or religious conviction that is not shared or not understood by other participants. In the above case, an additional factor may have compromised trust and prevented agreement between the ED physicians and the patient's family: cultural difference.

Culture determines how people view and make sense of the world, and how they experience health, illness, and medical care.³ Cultural beliefs and rituals help patients and families cope with the fear, stress, and grief of life-threatening illness by providing a context of meaning and a structure of support.

Physicians, too, hold strong cultural beliefs and values about the dying process and use of life-sustaining treatment. Thus, deliberation about such treatment, perhaps more than any other moment in the course of medical care, can make manifest latent cultural differences, latent mistrust due to a legacy of racism, and even latent racism. Caring for patients facing life-threatening illnesses is often a challenge to the physician's capacity for empathy.

Two Types of Cultural Difference

Cultural misunderstandings, as varied as cultures themselves, might be grouped heuristically into two general types: 1) those caused by different cultural practices; and 2) those caused by historical discrimination by one cultural group against another and by resultant mistrust.

The differences between minority and majority cultural practices that can lead to serious misunderstandings in medical care were highlighted in the same 1995 issue of the *Journal of the American Medical Association*. Carrese and Rhodes reported that exposing Navajo patients to advanced care planning as required by the Patient Self-determination Act and the principle of autonomy can inadvertently harm them.⁴ Physicians' unreflective insistence on the patient's right to know may lead in some instances to a cultural paternalism that can psychologically injure patients from some cultures.

Blackhall and colleagues found that members of some minority cultures were more likely than members of the majority culture to believe that only the family, and not the patient, should be told the truth about a diagnosis of metastatic cancer or a terminal prognosis, and that the family rather than the patient should make decisions about life support. The authors concluded that a family-centered style of medical decision making is common in some cultures and that physicians ought not, therefore, adhere blindly to the patient autonomy model. Rather, they must take care to learn the beliefs and preferences of each individual patient regarding medical decision making and to respect those beliefs and preferences.⁵

Several studies have reported a greater preference for life-sustaining treatment among African-Americans facing life-threatening illness than among European-Americans.⁶⁻⁸ Other studies have found consistently that African-Americans are less likely to have, or to be interested in, an advance care plan such as a living will, health care proxy, or DNR order.⁹⁻¹¹ Some investigators have proposed that these well-documented differences in preferences for end-of-life care are due to mistrust based on an historical context of racism and cultural discrimination.¹⁰

Is There an Historical Context for Culturally-based Mistrust of Physicians?

American medicine through history has not been immune to racism. In the 19th century, medical research purported to prove the inferiority of African-Americans and was cited to justify racial domination.¹² Antebellum physicians claimed that African-Americans had physiological and anatomical features (small brains; thick skin; high tolerance for heat, sun, and pain) that made them well-suited to be both slaves and research subjects.¹³

In this century, the Tuskegee Study (1932-72) sanctioned lying to African-American sharecroppers infected with syphilis and preventing them from receiving treatment.¹⁴ This disturbing history fueled mistrust of the medical profession by many

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African-Americans. Poorly conceived public health projects in recent years, such as sterilization initiatives in the 1960s and the sickle cell screening project in the 1970s, may have exacerbated the problem.¹⁵

Today, African-American and other minority patients have lower access to many medical services than majority patients in spite of the poorer overall health of African-Americans as measured by parameters such as infant mortality rate and life expectancy. Such medical services include management of chest pain and coronary artery disease, renal dialysis and transplantation, analgesia for acute trauma, and general outpatient and inpatient care. American medicine still has not proven itself entirely trustworthy.

Clear data linking culturally based mistrust to specific preferences for end-of-life care are scant. In a small focus group study, Hauser found that mistrust and suspicion about the health care system influenced attitudes of African-Americans toward advance directives.¹⁶ Yet these findings have not been confirmed in larger or quantitative studies.

Toward Minimizing Cross-cultural Misunderstanding and Mistrust

While empirical evidence is lacking that mistrust is a complicating factor in deliberations about life-sustaining treatment, clearly culture is important in determining preferences for such treatment. How, then, can a physician go about understanding the needs, fears, and preferences of patients and families of unfamiliar cultures? How can a physician minimize misunderstanding and mistrust and provide culturally sensitive care?

A place to start is the recognition that the basic principles, values, and assumptions of Western medicine and bioethics are themselves historically situated and culturally determined.¹⁷ They are the values of a dominant culture. When we recognize our own culture *as a culture*, we open ourselves to others.

Second, it must be recognized that *intra*-cultural differences are at least as great as *inter*-cultural differences. Only through dialogue with a patient or family can one assess the relevance of knowledge about a particular culture to which the patient appears to belong.¹⁸ Attending to the singularity of patients can be accomplished using an ethnographic approach.¹⁹ Eliciting a brief ethnography and the patient's understanding of his or her illness can provide insight into the patient's suffering, values, and preferences for life-sustaining treatment. This knowledge can facilitate negotiation of a treatment plan that is acceptable to both patient and physician.

Let us return to our case. In a clinical encounter between an upper middle-class, European-American physician and a working-class, African-American family, eliciting a brief ethnography and the patient's or family's understanding of the illness could uncover mistrust or other factors that may adversely affect the patient-physician relationship and the quality of care. Should mistrust be uncovered or suspected, the physician ought to be prepared to acknowledge that discrimination exists in the world but also to assert that it is unacceptable. The physician should reassure patients or surrogates that all reasonable options are available to her patients and that treatment plans will be worked out in dialogue with them.

On rare occasions, consideration may be given to overriding a surrogate's request for life-sustaining treatment. But this should be done only after a careful search for and consideration of relevant cultural, religious, and personal factors, only after bona fide efforts to win the surrogate's trust, and only if the patient's

comfort and dignity would be severely compromised by the life-sustaining treatment in question. A hospital ethics committee should be consulted to assist with this process. ■

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Emerging Risks of Genetic Testing

With genetics soon to become a basic component of medicine, an era of testing will be followed by new, individually tailored therapies based on an individual's genetic makeup. Genetics differs from other areas of medicine in several important ways (Figure 1), as do its risks.

Insurance and Employment

The most published fears are that genetic information will reach insurers and employers, causing discrimination against healthy people who may have expensive illnesses in the future. Almost all professionals and patients (in a survey of 1,084 geneticists and 476 patients) agreed that insurers, employers, and schools should not have access to information from an individual's genetic tests without that person's consent.¹ About one-third so distrusted these institutions that they said there should be no access at all, even with consent.

To date, no evidence indicates that insurers or employers are planning to use genetic testing. Most insurance companies get all the risk information they need from family histories. They require testing only in extraordinary circumstances, for example in individual applications for insurance (not via an employer) when the family history shows high risk for a late-onset, single-gene disorder, such as Huntington disease. People insured through their employers generally do not have to provide a family history.

Discrimination

Few of the surveyed patients or geneticists reported actual refusals of employment or insurance that might be considered "genetic discrimination." Most patient reports reflected general limitations set by insurance or employment practice, rather than special exclusion on genetic grounds. Examples included refusal to reimburse cosmetic surgery for children with Down syndrome or late-term abortions done out of state, because policies did not cover cosmetic surgery or out-of-state procedures, refusal to provide life insurance immediately after a heart operation, or refusal of employment as a firefighter to someone with chronic bronchitis.

The 1,084 genetics services providers—with a median of nine years in practice—reported a total of 550 refusals of insurance or employment solely on the basis of genetic status in the absence of symptoms. This suggests that such refusals compose only a small portion of insurance inequities.

Legislative Protections

Current federal legislation provides inadequate protection for people whose genes may predispose them to expensive diseases. The Americans with Disabilities Act (ADA) protects rights to employment, both for people with existing genetic conditions and people whose genes will cause significant disability later in life.² ADA does not apply to health insurance.

Of course, employment and health insurance are closely linked. The federal Health Insurance Portability and Accountability Act (HIPAA) allows people with genetic conditions who are already insured to transfer insurance from one employer to another, but does not prevent steep increases in premiums.

More protection is needed either through mandated extended insurance coverage or by protecting privacy of information. Federal legislators have chosen the privacy route. In the last Congress, 110 bills on genetic privacy were introduced. None reached a full committee, partly because of the difficulty of setting "genetic" information apart from other medical information. Broader bills on medical privacy may fare better. Meanwhile, keeping "shadow charts" for genetic information is legally dubious and may be harmful if such information is not conveyed to referrals.

Disclosure to Relatives

Genetics is a family affair. Relatives at genetic risk may be the parties most likely to inquire about an individual's genetic status. Although Western medicine usually regards the individual as the unit of privacy, genetics by its very nature threatens the individualistic paradigm. In some extraordinary cases, the professional should be ethically permitted (but not legally required) to override confidentiality if nondisclosure poses a high risk of serious harm to the relatives.

How Genetics Differs from Other Areas of Medicine

Figure 1

Genetics:

- Provides information about other blood relatives.
- Provides information predicting the future of persons who are now healthy, including children.
- Provides unexpected nonmedical information, such as nonpaternity.
- Has a history of "non-directiveness" in counseling.

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A more challenging problem is how to protect the relatives' right "not to know" possibly unwanted information they have not asked for. For example, genetic tests may incidentally reveal family secrets, such as nonpaternity. Most professionals and patients in the survey agreed that in the interests of preventing harm to the family, such information should not be disclosed unless the test was done specifically to determine paternity. Professionals had no consensus, however, about whether this possibility should be mentioned in the informed consent before testing.

Testing Children

Both the American Society of Human Genetics and the American Medical Association have issued statements to the effect that unless it is necessary for a child's or adolescent's treatment or reproductive decision making, genetic testing is best postponed until individuals are old enough to legally make their own decisions. Genetic testing for adult-onset disorders at the parents' request poses unwarranted social and psychological risks to the child.

How Patients' Views Differ from Professionals'

While protecting privacy may be paramount for the professional, patients may be more interested in getting care for their families and may be more oriented toward disclosure. In our survey:

- 96 percent of patients (mostly mothers of children with genetic conditions) would reveal to a school system a diagnosis of XYY, a condition once thought to be related to behavioral disorders or violence, on the grounds that this would help the child, as compared with 28 percent of professionals who would so disclose.
- 76 percent of patients—as compared with 38 percent of professionals—would tell the relatives of a patient with Huntington disease who refused to permit disclosure of the diagnosis.
- 74 percent of patients and 36 percent of professionals would reveal nonpaternity to a husband who asked directly.
- 43 percent of patients, compared with 20 percent of professionals, thought that a spouse should have automatic access to genetic information affecting the health of the couple's future children.

A series of consumer focus groups held by the New England Regional Genetics Group produced the list of consumer concerns in *Figure 2*. Two topics of great concern to genetics providers—privacy and non-directiveness—were not among the public's major concerns.

Genetic knowledge among physicians leaves room for improvement. Many of the 499 primary care providers surveyed were unaware of the functional aspects (ability to complete high school, hold a job, have biological children, live to adulthood) of even relatively common disorders such as cystic fibrosis or Down syndrome. Consumers do not necessarily expect a physician to know everything, but they do expect physicians to recognize their own limits and to know when and where to refer.

Suggestions for Reducing Risks

One way to increase accuracy and avoid the risk of a missed diagnosis is to update the family history at regular intervals. Usually the history is taken once, at the inception of a patient-physician or patient-HMO relationship, and then buried in a computerized medical record.

Family histories are not static. People do genealogical research, sometimes finding new relatives; grandparents, parents, and siblings die, with their final illnesses leaving genetic clues to a patient's future. Family histories should be regularly updated and discussed.

Increasingly, professionals will need to consider the presence of a genetic condition, and should not hesitate to refer to a specialist. Patients will want to be made aware of any social and economic risks, including

risks to employment or insurance. Their individual beliefs about privacy and disclosure, especially to family, should receive a careful hearing. ■

What People Most Want from Genetic Counseling

Figure 2

- 1 Accurate Information
- 2 Respect for persons
- 3 Providers who know their limits
- 4 Teamwork among professionals
- 5 Respect for client as a member of the team
- 6 Advice, direction, guidance
- 7 Awareness of family context
- 8 Referrals to sources of support

Notes & References

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Suggestions for Further Reading

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Bedside Rationing of Health Care Services

The unwillingness of third-party payers to explicitly say how they will contain health care costs means that the only way to decrease the inflationary effects of expensive medical advances is through implicit health care rationing. This will increase pressure on clinicians to ration at the bedside. If third-party payers increase their use of utilization review, this will increase bedside rationing, because clinicians will eventually have to decide whether to accept the recommendations of utilization reviewers. If third-party payers increase their use of capitation, this will only succeed through bedside rationing.

Even when third-party payers are willing to explicitly ration health care, they will still rely, at least in part, on bedside rationing. Outside the U.S., for example, many governments rely on relatively fixed budgets to control health care spending. Often, the spending limits are well known, which makes clinicians more likely to accept bedside rationing. For example, 87 percent of physicians surveyed in the United Kingdom agreed that “rationing of prescribed drugs should take the form of individual clinical decisions as part of the general practitioner-patient relationship, rather than depending on whether the practice has over or under spent its prescribing budget.”¹ In short, not only is rationing here to stay, bedside rationing is here to stay, too.

Deciding Which Services to Ration at the Bedside

Given the methodologic and moral limitations of cost-effectiveness analysis (CEA), what should clinicians do? How should they go about identifying marginally beneficial services which they can appropriately withhold from their patients? Clinicians have several points to keep in mind as they struggle to decide which services, if any, they will ration.

First, despite imperfections, CEA is a good place to start identifying marginally beneficial services to ration. CEA offers a reference point for comparing and judging medical interventions. With so many beneficial interventions to offer patients, CEA gives us an idea about how much money we must spend to get a certain amount of benefit. Clinicians should familiarize themselves with how to interpret cost-effectiveness analyses. Clinical schools and training programs should teach clinicians how to interpret CEAs. Knowing something about the basic science of CEA measurement is as important for clinicians as knowing the basic science of the Krebs cycle, and probably more important than knowing the Latin terms they are forced to memorize in anatomy class.

Second, clinicians need to be aware of CEA’s limitations. For example, CEA undervalues the benefits of life-saving treatments and of interventions directed at improving the health of people with severe illness or disability. If a life-saving therapy is equally cost-effective as non life-saving therapy, the life-saving therapy is probably more important to the public.

When a little girl falls into a well, no one asks how much it will cost to get her out; we simply do what we can to save her. The public places special importance of directing resources to identifiably and desperately ill patients. Indeed, bedside rationing is *inappropriate* when deciding whether to offer life-saving treatments to specific patients.

In recent years, there has been significant debate about whether doctors can ever morally justify a decision to refuse a life-saving treatment to a patient on the grounds that the treatment is “futile.” Experts disagree about what chance of success qualifies as “futile.”²⁻⁴ They agree that interventions with no chance of success are futile. But such interventions are extremely rare. While intensive care unit (ICU) care for someone recently decapitated is obviously futile, most of the time it is impossible to say that ICU treatment has a zero percent chance of success. No series of similar cases will prove that the next case will turn out the same way, so even if the last 100 patients admitted to the ICU with a similar illness have died, the next one may survive.³

However, one concept has been virtually absent from debates about futility—economics.⁵ This absence is informative. Although it is difficult to define what percent chance of success is “futile,” most interventions which approach zero percent chance of success are extremely cost-ineffective. If ICU treatment has a less than one percent chance of benefiting a patient, at a cost of tens of thousands of dollars per patient treated, the math is not too difficult. The cost per year of life saved will be extremely high.

Nevertheless, few people have wanted to frame futility debates in economic terms. Most people do not think decisions about whether to attempt life-saving therapy for identifiably ill patients should be based on cost. In contrast, decisions about whether, for example, to adopt new but expensive advances in Pap smear technology are based almost solely on their cost-effectiveness.

In short, when deciding whether to offer specific patients potentially life-saving surgery, ICU care, or other such treatments, American society has decided that money should not influence decisions. Thus, in these settings, it would be inappropriate to ration at

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This article is excerpted with permission from Dr. Ubel’s book, *Pricing Life: Why It’s Time for Health Care Rationing*, published by MIT Press.

the bedside. Instead, these decisions should be based on the balance of burdens and benefits to the patients, based on patients' values whenever possible.

If any rationing is to occur when deciding whether to offer expensive, potentially life-saving treatment to an identifiably ill patient, this rationing should not be done at the bedside; it should not be based on the discretion of an individual clinician. Instead, this rationing decision should be made at a higher level by a health care system or by government. It should be based on some kind of community consensus that this type of patient should not receive this type of expensive treatment.

Bedside Decisions

This is not to suggest that bedside rationing should be absent from ICUs. Many times bedside rationing can occur in these settings, such as in daily decisions about whether to order certain blood tests or X-rays. Bedside rationing is inappropriate when deciding whether to admit a specific patient to intensive care, not in deciding whether a low yield diagnostic test is worthwhile to do once the patient has been admitted to the intensive care unit.

I once took over the care of a patient whose previous primary care physician had tried to withhold blood products from him, on the basis that this man's quality of life was not good enough to justify his ongoing transfusion needs. This patient was seriously ill with severe congestive heart failure and a chronic bleeding disorder in his colon. He was ornery, and his family was even worse. Rumor had it that his family was trying to keep him alive only so they could collect his disability checks.

Although this was an incredibly challenging man to care for, it was totally inappropriate for this clinician to withhold blood products from him. I do not know how cost-effective it was to transfuse this patient. But I do know that his wife shared a bed with him, even though he was frequently incontinent of urine and stool. No disability check would compel most of us to do that. And I also know that this man and his wife loved each other very much; it was important for them to be with each other as long as possible. So even though this man's quality of life looked dismal to many clinicians taking care of him, he still enjoyed his life. When trying to conserve medical resources, clinicians need to be cautious about making judgments about whether a specific patient's quality of life is good enough to deserve resources.

Contrast the clinician in this case with one who decides not to aggressively pursue cholesterol lowering medications in patients at low risk of developing heart disease. Evidence is accumulating that most of us could decrease our risk of heart attack by taking cholesterol lowering medications. But people at low risk of developing heart disease—those without a family history of heart disease, who are not obese, and do not have high blood pressure or diabetes—receive these benefits infrequently.⁶

If a person only has a one percent lifetime chance of heart disease, therapy cannot reduce the heart attack risk by a large amount. For these low-risk people, the cost-effectiveness of cholesterol reduction is minimal. Clinicians who decide not to push for cholesterol reduction in these people will save the health care system significant money, while only having a small effect on the health of the population. Clinicians who ration cholesterol medications to low-risk patients are not making life and death decisions based on a patient's perceived quality of life. They are making population based decisions (with some attention to patients' specific factors) about whether scarce health care dollars are best spent on preventing MIs in people unlikely to ever have them.

Another consideration is in order when rationing at the bedside: clinicians need to pay attention to the organizational context of their rationing decisions. Rationing within the VA system is different than rationing at a for-profit health care company. This affects the justifiability and appropriateness of rationing decisions. (Indeed, clinicians need to get much more aggressive about debating institutional rationing policies and institutional financial policies. If health care companies want to aggressively maximize profits, clinicians need to step in to remind the institution of other priorities.)

Conclusion

Most issues about how to ration at the bedside have not been sorted out satisfactorily. For example, the role of informed consent in bedside rationing is not well understood. Research might illuminate how well clinicians can discuss these issues with patients and whether such discussions improve or harm clinician-patient relationships. But in the meantime, clinicians need to decide for themselves how and when to discuss cost containment efforts with their patients. We have been debating whether rationing is necessary for so long that we have not spent much time discussing how to ration. Ultimately, clinicians need to decide for themselves what their threshold is for offering small benefits to patients, and when they should discuss patients' out-of-pocket costs. But, with time, this personal judgment will, we hope, be informed by rational public debate, and even data, about bedside rationing. ■

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Informed Consent

A Jehovah's Witness received blood transfusions during treatment for necrotizing pancreatitis.

Clinical Sequence

A 39-year-old woman was admitted to the insured hospital with necrotizing pancreatitis. She had significant blood loss and a dropping hematocrit. With the severity of her condition, death was a likely outcome. Both the resident and the attending were aware the patient was a Jehovah's Witness. The patient had been intubated and was in ICU. She was told by the attending he would not perform surgery without a blood transfusion, and that without the surgery, she would die.

The insured attending felt the patient was competent when she nodded her consent for a blood transfusion. The physician contacted the hospital's in-house counsel, who recommended doing "what was medically necessary." The patient had written a note to her husband stating "please don't let me die." The husband, who was not a Jehovah's Witness, also gave permission (orally) for the blood transfusion.

After permission was obtained, the patient was taken to surgery and given blood transfusions. Over a three-and-a-half month hospitalization, the patient underwent more than 20 procedures with more than 30 transfusions.

Claim Sequence

The patient filed a lawsuit against the resident, the surgeon, and the institution alleging that the transfusion of blood products against her will constituted an invasion of privacy, battery, and a civil rights violation. Prior to trial, the institution was dropped from the suit and the counts of invasion of privacy were dismissed.

Disposition

After a favorable tribunal, the case went to trial where the jury found in favor of the defendant physicians.

Discussion Points

Informed Consent 1

Family members and Jehovah's Witnesses testified that the blood transfusions disregarded the patient's wishes.

Generally, refusal of blood and blood products by an adult, competent Jehovah's Witness must be respected and may only be overridden by a court order, in non-emergency situations. Involving the institution's legal counsel or medical ethics committee can help clarify the decision making during emergencies.

If previously treating providers knew her wishes about blood transfusion, discussion and documentation of her preference could have been helpful in this emergency. Such a discussion should be considered for patients with chronic diseases that may lead to emergency situations, such as whether an asthma patient would want to be intubated.

Informed Consent 2

Consent was obtained from the patient while she was intubated.

A patient's non-oral or written consent (e.g., by nodding) should be carefully documented in the record along with the names of any identified witnesses.

Informed Consent 3

Based on a note written by the patient, her husband gave permission for her blood transfusion.

Any mentally competent person 18 years or older has the right to consent to his/her own medical treatment, and is the only person whose consent is valid. Consent given by proxy should be documented (i.e., a copy of her note should have been added to her medical file).

Informed Consent 4

This patient was treated with multiple procedures and transfusions based on a single act of consent.

Generally, clinicians are not required to engage patients in an informed consent discussion for each occurrence of a repetitive procedure or treatment, as long as the clinical indications and risks are unchanged. However, when the initial consent occurs in the midst of an emergency, and the treatment consented to must be repeated during subsequent care, the consent process should be revisited and documented.

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