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Patients and Doctors — The Evolution of a Relationship

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The relationship between patients and doctors is at the core of medical ethics, serving as an anchor for many of the most important debates in the field. Over the past several decades, this rela-

tionship has evolved along three interrelated axes — as it is defined in clinical care, research, and society. Many of the pivotal discussions of these issues have appeared in the pages of the *Journal* (see box).

CLINICAL CARE


The relationship between patients and doctors in the clinical realm has historically been framed in terms of benevolent paternalism. Until about 1960, most codes of medical ethics relied heavily on the Hippocratic tradition, framing the obligations of physicians solely in terms of promoting the welfare of the patient, while remaining silent about patients' rights. The past several decades

have seen tectonic societal shifts that have resulted in increasing empowerment of individuals against the authority of government and institutions, creating a surge of rights-based movements, with patients' rights emerging as a societal demand alongside women's rights, minority groups' rights, consumers' rights, and others.

This dramatic shift appeared to move the locus of authority in decision making from the physician to the patient. And indeed the emergence of the Internet, with its myriad health-related websites and other sources of medical information, has given many patients the impression that they can largely manage their own medical affairs, with physicians serving primarily as consultants. But the reality is more complex: the wealth of information available to patients has proved to be

as dangerous as it is helpful, and today patients and physicians are beginning to find a healthier balance of power through a process of shared decision making. With this approach, physicians are seen as having expertise and authority over matters of medical science, whereas patients hold sway over questions of values or preferences.

This division of labor reflects a recognition of the naturalistic fallacy, the erroneous notion that one can derive ethical conclusions from scientific facts; in truth, an "ought" cannot be deduced from an "is." Although physicians may be experts on the medical facts of a patient's condition, those facts are never sufficient to specify a course of treatment; clinical decisions must always include consideration of the values and preferences of the patient. This approach has many implications — for example, in recognizing the right of a competent adult to refuse a lifesaving blood transfusion on the basis of his or her religious beliefs, or the right of a patient

 An audio interview with Dr. Truog is available at NEJM.org

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to refuse mechanical ventilation for a treatable and reversible cause of respiratory failure. Stated succinctly, today we acknowledge that competent patients have a virtually unlimited right to refuse unwanted medical care, even when physicians correctly claim that it would be medically effective and indeed even lifesaving. More important, however, is the way that

the concept of shared decision making guides the many more mundane decisions that are made in clinics every day, when physicians present patients with what they see as reasonable medical options and then help them to incorporate personal values and preferences to arrive at decisions that make the most sense for them in terms of both the medi-

cal facts and their unique personal perspective. This approach to engaging patients has other benefits as well, such as promoting their sense of self-efficacy and improving their adherence to treatment recommendations.

Despite this vigorous consensus about the rights of patients to refuse unwanted care, equally strong disagreement persists about patients' rights to demand care that physicians regard as medically inappropriate. Consider situations in which the data clearly show that the likelihood of successful resuscitation would be less than 1%. Does this fact allow us to conclude that resuscitation should not be performed, regardless of the patient's preference? Or is the threshold for what should count as a reasonable likelihood of success fundamentally a question of value that should be defined by the patient? When the medical evidence overwhelmingly suggests that a patient is permanently unconscious, does this imply that further medical treatment is inappropriate and should not be provided (as stated in the guidelines of many professional societies), or is what counts as a "life worth living" a personal choice that should be respected?

In recent years, the Texas Advance Directives Act has defined one very concrete approach to addressing these dilemmas. When families demand treatments that have an exceedingly low likelihood of success or that sustain life of such low quality that one might reasonably say it is of no benefit to the patient, Texas law allows physicians to refuse to provide such treatments. Under the Texas legislation, demands by families for treatments that appear to meet these criteria are adjudicated by a hospital-based committee, and if the committee agrees with the

clinicians, and if other providers cannot be located who are willing to provide such care, then treatment may be withdrawn without the permission of the patient's surrogate. Although Texas has the most experience with this approach, other states are showing interest in similar proposals that address both the financial implications of providing allegedly inappropriate care and the concerns of clinicians who must endure the moral burdens and burnout associated with being compelled to provide treatments they believe are ethically wrong.

CLINICAL RESEARCH

The Nuremberg trials in 1946 marked the beginning of modern discussion of the ethics of clinical research. Although Nuremberg showed how physicians could be led astray by a corrupt political regime, it was not until Henry Beecher's alarming exposé in 1966 that U.S. physicians had to confront the fact that blatantly unethical research — such as injecting patients with malignant cells without their knowledge or permission — was prevalent even on the wards of prestigious academic medical centers in the United States.¹ These and other revelations led to the development of the principles outlined in the Belmont Report, federal regulations governing the conduct of clinical research, and the creation of institutional review boards charged with applying these guidelines to individual research protocols.

Despite the strong safeguards that are now in place to ensure that patients are fully informed and provide their consent before being enrolled in research trials, important tensions remain between the ethical obligations of the physician–patient relationship and those of the researcher–sub-

ject relationship. Both physicians and patients have a psychological tendency to minimize these tensions; neither wants to recognize the important ethical conflicts that may exist between clinical care and research. This phenomenon, known as the therapeutic misconception, has been shown by Paul Appelbaum and others to be ubiquitous among both researchers and research subjects, manifesting as the false and often implicit belief that the primary aim of research is to benefit the patient.² Although patients often do benefit from their involvement in research, nearly all clinical research includes procedures that carry risks to subjects that are not compensated for by corresponding benefits. By definition, research protocols are designed to answer scientific questions, not to optimize the medical care of the patient.

The concept of clinical equipoise was developed with the promise of easing the ethical tension between clinical care and research. Clinical equipoise exists when there is genuine uncertainty in the medical community about which of two treatments is better in a given situation. When this condition is satisfied, a researcher enrolling his or her patients in a randomized trial can honestly say to the patient, “Although I may personally prefer treatment X, if you were being seen by another, equally competent physician, you could be given treatment Y. Hence, your medical care will not be compromised if you agree to enroll in this trial and have your treatment determined by chance.” Under clinical equipoise, there appears to be no conflict between the ethics of clinical care and those of research.

Over the past several years, however, clinical equipoise and

other attempts to harmonize the ethics of clinical care and research have become less tenable, particularly in the context of placebo-controlled trials. Consider, for example, placebo-controlled trials of new antidepressants. Given that some antidepressants are known to be efficacious, clinical equipoise cannot be used to justify such trials, since a physician could never defend prescribing a placebo for a patient outside of the trial.

These problems extend beyond placebo-controlled trials, however. For example, oncologists have recently been engaged in an anguished debate about the ethics of a randomized, controlled trial of a new drug for metastatic melanoma in the face of impressive preliminary evidence supporting the efficacy of the new drug, in combination with the known dismal prognosis associated with the standard therapy given to patients in the control group.³ Trials like this one strain the concept of clinical equipoise beyond the breaking point: most oncologists would agree that these trials must be performed, but few would say that the physician researchers believe the treatments are in equipoise.

Given the scientific and ethical rationale for these trials and the failure of the clinical equipoise paradigm to provide justification for them, over the past several years a new way of looking at the ethics of clinical research has developed — one that regards the ethical principles governing clinical care and research as fundamentally distinct and indeed often in tension.⁴ If physicians forthrightly inform patients that the goal of clinical research is not primarily to optimize their clinical care but to advance knowledge for the benefit of future pa-

tients, both patients and physicians may be guided to a more transparent view of research that is not distorted by the therapeutic misconception.

Separating the ethics of research from clinical care has other advantages. With this approach, patients become more active participants in the research enterprise. They expect to be informed about research results and engaged in setting research priorities. Parallel to the evolution of the relationship between physicians and patients in clinical care, this new vision of the ethics of clinical research moves research subjects out from under the paternalistic umbrella of clinical investigators and empowers them to have a more equal and active role in the process of advancing medical knowledge.

POPULATIONS AND HEALTH CARE SYSTEMS

One of the most revered principles in medical ethics has been that physicians should be exclusively devoted to the best interests of their patients. As Norman Levinsky put it, “Physicians are required to do everything that they believe may benefit each patient without regard to costs or other societal considerations. In caring for an individual patient, the doctor must act solely as that patient’s advocate, against the apparent interests of society as a whole, if necessary.”²⁵ In reality, this has never been more than a lofty ideal, since physicians have always had competing pressures that prevent them from providing everything that might be of medical benefit to a patient, beginning with the fact that no physician can spend an unlimited amount of time with any one patient.

But this ideal is itself coming

under increasing scrutiny, as both physicians and society come to recognize that the benefits of a solely patient-centered focus to care must be balanced against the value of offering entire populations of patients equitable access to necessary health care.

The issue first arose in U.S. politics in 1962, when dialysis became available for only a limited number of patients and the public was horrified to learn that a small committee of anonymous citizens was tasked with deciding who should live and who should die. Rather than face this difficult problem head on, Congress eventually passed legislation mandating that renal-replacement therapies be fully funded by the government, a decision that stands to this day. Clearly, however, taking this approach to solving every rationing decision would lead to financial disaster.

More recently, the patient-versus-population dilemma played out over new recommendations for screening mammography. Although analysis shows that current screening practices are exceptionally cost-inefficient, there is no doubt that they have saved the lives of many women. Yet given the seeming impossibility of having a public debate about when it may be permissible to forgo some beneficial care that is very expensive in favor of providing other benefits that are a much better value, those who supported the new screening recommendations were forced to justify them solely in terms of what would be best for an individual woman, regardless of cost. Not surprisingly, by acceding to the taboo that renders open discussion of cost-effectiveness off limits, proponents of the new recommendations appear to have lost the debate.

The United States already

spends more on health care than any other country on earth yet does not attain the health benefits that are achieved in many countries with much more limited resources. By refusing to bring the issues of cost-effectiveness and rationing into the political discourse, we allow the myth to persist that there is some yet-to-be-discovered alternative to a thoughtful and systematic approach to the allocation of resources. Despite Levinsky’s seductive view that the relationship between physicians and patients should be isolated from any external pressures, we must recognize that population-based factors such as justice, efficiency, and fairness are also ethically relevant. Overcoming our inability to muster the political will and courage to acknowledge the necessity of rationing and to grapple with the best way to use the tremendous resources currently being devoted to health care is likely to be the greatest challenge in the evolving relationship between physicians and patients in the decades to come.

Although the relationship between patients and doctors is often idealized in terms of universal and timeless principles, it has not been immune from the larger social and cultural forces surrounding it. This relationship has been profoundly shaped by the human rights movement of the past several decades, and clinical care today is guided by norms of shared decision making rather than benevolent paternalism. Clinical research is no longer regarded as a side benefit of providing patients with clinical care, but rather as a compatible but distinct activity that requires us to view patients as partners in the process of advancing medical knowledge. And finally, the greatest challenge still lies largely be-

fore us, as we will struggle in the years to come to balance the personal advocacy that all patients rightfully expect from their physicians with the equally compelling obligation of physicians to see that health care resources are used wisely in ways that are efficient and fair.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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What We Talk about When We Talk about Health Care Costs

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Physicians have a responsibility to practice effective and efficient health care and to use health care resources responsibly. Parsimonious care that utilizes the most efficient means to effectively diagnose a condition and treat a patient respects the need to use resources wisely and to help ensure that resources are equitably available.

— American College of Physicians Ethics Manual: Sixth Edition, 2012¹

New ethics guidelines from the American College of Physicians (ACP) calling for physicians to practice “parsimonious care” have reignited a debate about the role and responsibility of physicians in addressing the country's problems with health care costs.¹ The ACP argues that the guidelines will help physicians to consider more carefully the tests and treatments they order and prescribe for patients and to think on a higher level about the well-being of the community at large.² Others have balked at the term “parsimonious,” viewing it as implying that care should be withheld and that society should be

stingy about how resources are allocated for health care.²

The debate reflects the larger struggle in the United States over how to deal with — and talk about — health care costs. U.S. political leaders are generally at pains to assure Americans that proposed health care reforms will not reduce their benefits nor curtail their choices. Health care costs are a major problem, they admit, but the way out of our dilemma is to deliver more efficient, more effective, and safer care and to reduce waste.³

There is a sturdy logic to these arguments, beyond their obvious political advantages. Research has revealed nonadherence to clinical guidelines, variations in practice patterns, preventable errors, and unnecessary hospitalizations. There is an overwhelming case for being smarter about how we finance and deliver care.

The problem is that no one in charge seems willing to acknowledge that getting a handle on cost growth will also involve uncomfortable trade-offs. We cannot as a society provide patients with unlimited access and unlimited choice. Providing better-quality care, though it is vital, won't change that reality.

The language of the Affordable Care Act highlights the dilemma. The law states, for example, that the newly created Independent Payment Advisory Board, established to recommend spending reductions for Medicare, cannot change benefits, shift costs to patients, or ration care. The law created a Patient-Centered Outcomes Research Institute (PCORI) to conduct comparative-effectiveness research but specifies that the secretary of health and human services cannot use it as the sole basis for denying coverage for items or services. The Affordable Care Act forbids the PCORI and the Department of Health and Human Services from using cost-effectiveness thresholds.

The inclusion of “patient-centered” in the name of the PCORI underscores the issue. On the one hand, the focus on patients has clear benefits, apart from its inspired branding. As PCORI Executive Director Joseph Selby recently observed, “The notion that patients could be at the center of a research enterprise is pretty different from the way research has rolled out over the past century.”⁴ The idea is to concentrate on outcomes that patients view as important. The PCORI web-