

New Ethical Dilemmas

With increased emphasis on quality measurement and pay-for-performance, physicians are encountering new ethical dilemmas.

Chapter in Brief:

- ▲ *As payers and licensing boards put more emphasis on accountability and the collection of performance and health outcome data, physicians may feel that they are increasingly being put in the middle between patients and regulatory authorities.*
- ▲ *Pay-for-performance (P4P) program initiatives can be structured ethically, physician leaders maintain, if patients are informed properly and if the programs are designed to reward coordinated, patient-focused care.*
- ▲ *Quality improvement (QI) initiatives are also sparking concerns largely because they're not research in the traditional sense, but they do involve issues of consent and privacy.*
- ▲ *New business approaches—such as selling health-related products or starting a concierge practice—raise ethical questions.*

Until about a decade ago, most physicians who practiced outside of academic settings were largely on their own in determining how they ensured their own professional competence, pursued their continuing medical education, and applied the medical knowledge they had attained in training or during their career. The assumption was that a self-regulating profession, by its nature, commits to ethical conduct and continual self-assessment and self-improvement, and holds itself accountable to those it serves—which is the public, in the case of physicians.



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The same attitude largely held true on the business-operations front, in that physicians were generally free to run their practices as small businesses in whatever manner they chose, provided they did not violate the law or run afoul of governmental or commercial payers' requirements.

Things are changing on those fronts, and new ethical challenges are emerging as a result. Oversight bodies, traditionally focused on measuring quality in care-delivery settings, are turning their attention to individual physicians. Medical specialty boards are moving rapidly toward a system of continuous skills

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and competence measurement as a condition of certification, and licensing entities are joining in the effort. Physicians are being held more accountable for measuring and reporting their own performance—mostly in the form of quality-improvement or health-outcomes data—to various third parties.

“We may be at a historic moment in terms of how things are changing for physicians,” observes researcher Timothy Ferris, MD, MPhil, MPH, assistant professor of pediatrics and medicine at Harvard Medical School and the Institute for Health Policy in Boston. “Medicine is moving from a cottage industry to a corporate one, and along with that come interesting dynamics—in everything from health policy to medical professionalism.”

On the professionalism front, accountability pressures and pay-for-performance programs are colliding head on with the long-held view that medicine should—and can—regulate and monitor itself, Dr. Ferris contends. He believes that physicians have been historically weak on some aspects of self-regulation, and he points to various studies to back up his claim.

“The pay-for-performance dynamic is shifting by forcing doctors to accept some degree of external accountability,” continues Dr. Ferris, who writes frequently on ethics issues in health

services delivery and utilization, and is medical director of the Massachusetts General Physicians Organization. “That is a complete sea change from five years ago, and in terms of the ethics around professionalism, the major change is that the pillar of self-regulation is getting stronger by the minute.”

Physicians in a Tough Spot

One of the driving forces in the rapidly evolving arenas of performance measurement and quality improvement (QI) is an economic one, Dr. Ferris and others maintain: the evolution of the healthcare payment system. As the government and employers assume an ever-rising portion of healthcare costs, Dr. Ferris says, “The [entities that] are paying have a fiduciary interest in understanding the quality of care they’re paying for—but they don’t necessarily have the patient’s perspective.”

In that confluence of factors and competing interests, physicians frequently feel caught in the middle and consigned to shaky ground ethically as they try to serve multiple constituencies: patients, payers, regulators, and accrediting organizations. The pressure to increase patient volume or alter referral patterns can compromise the doctor’s ability to honor the doctrine of patient primacy, for example.

“The issue of patient primacy is extremely important in this era of very difficult economics, especially with the encounter-based payment system. It’s not just a matter of resource allocation,” says Frederick Turton, MD, chair-elect of the American College of Physicians board of regents and former chair of the college’s ethics committee. The encounter-based system, particularly at the low end of the payment scale of primary care, Dr. Turton explains, stimulates “churning,” i.e., seeing patients more often, seeing more patients per day, or both.

“If you do a bad job, you do better financially because you get to see the patient again. That’s a serious violation of professionalism, but incentives are important in this world,” Dr. Turton, a Sarasota, Fla., internist, says. “Basically, you don’t get paid for doing the right thing if the right thing is nothing. That’s one unintended consequence of the current payment system.”

The nascent movement toward creating an “advanced medical home” that recognizes the importance of primary care physicians

(PCPs) in managing patients' overall care, and compensates accordingly, may alleviate some payment system inequities that are eroding primary care, Dr. Turton allows. But the concept is just beginning to gather steam, and the initiatives that have been launched are only in pilot stage.

Productivity pressures that pose ethical challenges aren't just external, however. Increasingly, medical groups measure their physicians' productivity from a bottom-line financial standpoint. Many groups then publish individual physicians' income and charges relative to their colleagues', and charge overhead accordingly on a proportional basis. Such structures are "ethical and appropriate as good business practices," Dr. Turton concedes, but they can challenge the physician's professionalism.

"There are a number of inherent ethical conflicts in pay-for-performance. The concern is that if these programs become the rule rather than an experiment, there could be serious issues that someone—providers and those structuring the programs—have to deal with," says Richard Neubauer, MD.

"The doctor gets caught between being loyal to the group and weighing his own income needs. And those things get balanced against professionalism" he says.

As P4P structures and programs proliferate, physicians find themselves facing ethical challenges on several fronts. For one, narrowly focused P4P programs—those that create incentives for improved management of a limited number of chronic diseases, for example—may prompt physicians, wittingly or unwittingly, to inordinately focus efforts on those diagnoses.

More problematic from an ethical perspective is the potential for patient "deselection" to boost personal financial gain from P4P, many physician leaders point out. That is a practice by which physicians either avoid taking on patients who are very ill or unlikely to be compliant with recommended treatment, or try to convince them to voluntarily leave the practice.

Even supporters of P4P as a concept have raised concerns about the effect of such programs in two important ethical domains: patient primacy and disclosure. Physicians scurrying

to meet P4P targets in diabetes or congestive heart failure may become so focused on the measures themselves during a patient encounter that they lose sight of the “whole patient”—or fail to adequately address the patient’s agenda for the visit. Even if that “unbalance” doesn’t occur, many physicians are understandably concerned about how and in what detail they should disclose to patients their participation in P4P programs.

“There are a number of inherent ethical conflicts in pay-for-performance. The concern is that if these programs become the rule rather than an experiment, there could be serious issues that someone—providers and those structuring the programs—have to deal with,” says Richard Neubauer, MD, an Anchorage, Alaska, internist who frequently writes on ethical issues in clinical practice and who recently co-authored a position paper on P4P principles.

“If all your patients are in a P4P structure, and you have the freedom to decide whom you pick as patients and are selective, that becomes a big ethical problem,” Dr. Neubauer says. “If the programs involve a limited number of patients and the monetary differentials are small, it’s less of an issue. But when someone is paying for things to be a certain way, there is a powerful incentive to make it work.”

A possibly more problematic ethical issue, Dr. Neubauer adds, is what happens to the big picture when P4P structures aren’t properly aligned with the goals of good overall patient care. “That’s the other question. Ethically, does one thing happen at the expense of other things?” Dr. Neubauer asks. He gives this classic example: A P4P program involving physicians who are treating patients with diabetes may require that a certain percentage of patients meet target hemoglobin A1C levels before an incentive will be paid. Even though meeting target levels could be construed as improving care, there could be unwanted consequences. “If that becomes the specific measure that determines whether you get paid X or X plus 20 percent, you can bet your bottom dollar you’ll get numbers and improvements,” Dr. Neubauer explains. “But then if you survey patients as they’re coming out the door and ask, ‘Did you receive good medical care?’ they might tell you, ‘You know, the only thing that doctor was interested in was my hemoglobin A1C. I wanted to talk

about my impotence.”

The American Medical Association and the ACP are among the physician organizations that have called for greater transparency in and oversight of P4P programs to ensure that patients aren't compromised in this way. Such programs can be structured ethically, physician leaders maintain, if they reward coordinated, patient-focused care and not simply performance on specific measures. “That’s an inherent problem with P4P—you get what you pay for,” Dr. Neubauer says. “And if an industry or society is defining something in a way that doesn’t fit with or threatens a physician’s ethic, that’s a dilemma.” In such cases, physicians should be allowed to opt out, and they should not be penalized for doing so.

The American Medical Association (AMA) has taken the position that if done correctly and ethically, P4P can improve care. But if it’s primarily used as a cost-reduction mechanism for payers and insurers, and if providers are “tiered” by health plans according to their P4P rankings, patient primacy and care access could be negatively affected, says James Rohack, MD, AMA’s president-elect.

“If these programs put a wedge between physicians and patients, they won’t achieve what they are supposed to achieve,” says Dr. Rohack, a cardiologist at Scott & White Clinic in Temple, Tex. He cites the example of a diabetes P4P program in the Midwest in which an insurer ranked physicians based on the number of diabetes patients under their care. Those who didn’t meet participation targets were placed on a tier requiring a higher co-payment, therefore making it more costly for plan members to remain with that physician. “If that means that 100 patients won’t have access to their physician without paying a higher copayment, there are ethical and access issues.”

The AMA’s basic position is that if the P4P program isn’t designed on evidence-based guidelines, or if patients who are at high risk for treatment non-compliance or poor outcomes could be disadvantaged, physicians shouldn’t participate, Dr. Rohack explains. “And the AMA has developed P4P ethics principles to back their decision,” he adds.

Another ethical concern raised by the AMA and others is that P4P programs in more profitable service areas could worsen the

already problematic distribution of resources—moving funds toward what pays and away from services that have historically caused doctors to lose money. “That’s a big-picture issue, when two hospitals in the community both have [cardiac] catheterization labs, but neither has any psychiatric beds,” Dr. Rohack says.

When the AMA asked members to share their experiences with P4P and quality improvement initiatives, physicians cited concerns about patient rights and privacy, Dr. Rohack notes. In

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the case of depression, for example, if insurers had lists of all patients on antidepressants and initiated phone calls to those patients to gauge compliance with treatment, some physicians ended up in an ethically uncomfortable position. “There have been cases where the patient calls and says, ‘Doctor, did you tell them my diagnosis?’ That’s the sort of testimony we heard in reference committees when we were developing our pay-for-performance principles,” Dr. Rohack reports.

Quality Improvement or Clinical Research?

QI initiatives, while not nearly as controversial as P4P, are also sparking concerns among ethicists and practicing physicians. A commitment to QI is one of the ethical principles espoused by all physician organizations, and it is presumed that doctors will do their part to advance care improvement. Ethical conflicts are emerging, however, largely because of the gray area in which many QI programs reside: They’re not research in the traditional sense; but because they involve patients, directly or indirectly, there are issues of consent and possibly privacy.

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continuous movement to higher levels of performance. That means every physician should be doing QI work all the time, in every possible way.”

Few physicians would dispute that, of course, and many cannot opt out because both Medicare and the Joint Commission require QI participation, and large health systems such as Kaiser and InterMountain Healthcare have long incorporated QI programs into their delivery systems.

The ethics concern is that QI has moved well beyond a personal professional consideration in recent years and uncomfortably closer, some say, to traditional clinical research. As QI has developed into a discipline and science, Dr. Davidoff explains, organizations have embarked on bigger, more complex endeavors “that involve patients in a new way. And that gets people’s attention because they feel that if you will be collecting data to show you’ve improved things and are involving patients and doing things in a new way, that’s research.” And if that’s the case, the question becomes whether the project should be granted some equivalent of institutional review board (IRB) approval before it proceeds.

“That’s where the tension comes from,” Dr. Davidoff says, for both the sponsoring organizations and the physicians whose patients are unwittingly involved.

The more pressing concern for physicians, however, is the potential, unprecedented ethical conflict in the informed-consent arena. Even if patients who are included in a QI project aimed at reducing infections aren’t specifically identified, should they be notified of the project and asked to consent to their involvement—especially if there is any potential for harm?

“Physicians who do QI in facilities are very concerned about this—and the human subjects protection regulations. They want to know what exactly they’re supposed to do,” says Mary Ann Baily, PhD, a research scholar and economist at The Hastings Center, a nonprofit bioethics institute in Garrison, N.Y., who recently co-authored a report on the subject. A recent, successful QI project aimed at reducing central-line infections in Michigan hospitals, and an earlier one involving dialysis care in end-stage renal disease in Pennsylvania, made headlines when some claimed that IRB review should have been required in advance.

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Dr. Mazzullo

Lisa Mazzullo, MD, OB/GYN,
Feinberg School of Medicine,
Northwestern Memorial Hospital

&



Dr. Streicher

Lauren Streicher, MD, OB/GYN,
Feinberg School of Medicine,
Northwestern Memorial Hospital

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“The reason this matters for practicing physicians is that even if they don’t end up doing their own QI projects, they will surely be brought into other people’s projects,” Ms. Baily explains. “If they’re attending doctors at a hospital and that hospital ends up doing QI, they must decide whether to cooperate.”

Even though the U.S. Office for Human Research Protections (OHRP) weighed in on the controversy, Dr. Baily notes, the agency didn’t offer definitive guidance to physicians who are concerned about their responsibilities and patients’ rights in QI projects. “They really didn’t say what to do next time—and that’s the concern,” she says. Until that issue is resolved, she urges physicians to turn to The Hastings Center’s recommendations regard-

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ing the ethical requirements for protecting patients included in QI initiatives. The four core ethical obligations are the following:

1. Every member of society must have an adequate array of core healthcare benefits.
2. The contents and limits of healthcare benefits must be established through an ethical process.
3. The healthcare system must be sustainable.
4. The healthcare system must ensure that its stakeholders have clear responsibilities for which they are accountable. (The full report, “The Ethics of Using QI Methods to Improve Health Care Quality & Safety,” is accessible at www.thehastingscenter.org/Publications/SpecialReports/.)

For his part, Dr. Davidoff recommends that physicians pursue a largely practical approach to deciding what is QI, what is research, where there might be overlap, and when patient protections are warranted. Following are his tips for physicians who are trying to decide whether a project qualifies as QI or research:

- Even if people are doing QI of an informal kind, consider

whether it should get some independent look to ensure it isn't doing something potentially harmful to patients.

■ Determine whether the identified improvement really is a part of clinical practice. “If you think it is, then the same mechanisms that make clinical practice ethical could be applied to decide whether QI projects are ethical, in the simplest terms.”

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Finally, Dr. Davidoff urges physicians to take a hard look at the privacy aspects of the QI project at stake. “This really is affecting physicians' lives, because most of what's done in QI that involves patients directly involves getting information from patients' charts. So there are privacy issues, too,” he says, adding that there are a “variety of ways to get appropriate waivers from HIPAA requirements if doing clinical-type research.”

Office-based Challenges

As clinical trials increasingly move out of the academic center and into doctors' offices and stand-alone testing centers, ethical challenges abound. The recent Hastings Center report, “Research in the Physician's Office: Navigating the Ethical Minefield,” points to a number of ethically problematic areas—from determining whether the trial itself is valid to ensuring proper informed consent and patient safety. Lois Snyder, JD, and Paul S. Mueller, MD, authors of the March-April 2008 report, cite a 2005 survey that found a substantial deficit in community practicing internists' knowledge of research ethics and practices. Only 79 percent reported having received formal training in informed consent, and just over half (51 percent) had been trained in research misconduct.

As such, physicians may—and often do—find themselves ill prepared to assess their readiness to participate in office-based research and the ethical appropriateness of that participation. Conflicts can arise when the physician is both the patient's doctor and a researcher. To make their way across that minefield, the report authors suggest, physicians might start by asking (and

obtaining answers to) the following questions:

- Will the trial or study, as designed, answer the research questions it asks?
- Are those questions worth asking—in the sense that the answers will contribute to scientifically valid, worthwhile knowledge and will advance patient care?
- Has the trial received IRB review and approval?
- Are the financial arrangements ethical, and is the prospective physician compensation fair market value? (For example, many ethical codes advise against accepting finder's fees for enrolling patients in trials, and call for full disclosure of physicians' financial ties to sponsors.)
- At the conclusion of the research project, where will results be published, and who will serve as author of the article(s)?
- Will the results be published in their entirety, or may there be restrictions on which results appear?

It's also important to ask how safety issues or adverse events that occur during the trial will be communicated to all participants, so that physicians who deem the risks too great to continue can advise their patients to withdraw in a timely manner. In the report, the authors also urge physicians to be wary of offers to participate in post-marketing research, an area potentially rife with conflicts. While certain research projects are clearly intended to assess device or medication safety over the longer term, government reports suggest that some appear to be conducted as a means of increasing prescriptions.

Avoiding Conflicts of Interest

In the last two years especially, concerns about conflicts of interest in the areas of medical research and patient care have spawned considerable discussion. As a result, numerous entities are taking a closer look at how relationships with commercial interests may inappropriately influence patients' medical care or research. Two areas that have received attention are medical research and CME funding.

Most physicians take advantage of CME opportunities for the right reasons, Dr. Fitzgerald says, but she has witnessed the other end of the spectrum as well. "I remember a group of young interns who had returned from an industry-sponsored meeting

and admitted that they ‘just did the vacation thing.’ When I asked if they thought that was OK ethically, the response was, ‘Everybody does it,’” Dr. Fitzgerald recalls. Changes in the CME realm, particularly new requirements regarding self-assessment and performance measurement, may help stem this misuse.

Reports of researchers who received huge sums in consulting fees or for speaking engagements and didn’t report the funds, for example, have prompted academic institutions to implement strict conflict-of-interest policies. A study by Columbia University researchers published in the Sept. 3, 2008, issue of the *Journal of the American Medical Association* found that 25 medical centers had either substantially strengthened such policies or developed new ones, and that many other institutions were in the process of doing so.

Typically, new policies not only ban physicians and researchers from accepting travel reimbursement and meals, but also prohibit doctors from ghostwriting articles about products

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or devices and engaging in questionable consulting arrangements. Increasingly, academic medical centers are also limiting drug-sample distribution. In addition, state and federal government have stepped in to require closer scrutiny of physicians’ and institutions’ relationships with industry and public reporting of associated income.

Physician organizations generally support more stringent oversight of industry-sponsored research arrangements. But some groups think that the undue-influence argument—that physicians will make treatment decisions based on a single sponsored presentation or accept inducements—is overstated. “This is an active area that a number of organizations are looking at closely, but it’s important to maintain a perspective,” says James Rohack, MD, president-elect of the American Medical Association.

tion. “The issue is not about physicians’ receiving money [for presentations]. The issue is that they should disclose where the money is coming from, and let the learners make their determination of whether there’s undue influence.”

Dr. Rohack, who is a cardiologist, gives an example: “If a researcher is pushing a product as the best thing since sliced bread, but I see that he is on the speakers’ bureau and is receiving an honorarium, I will take that into consideration,” he says. On the other hand, if the presentation is funded through an unrestricted grant to the university, Dr. Rohack explained, “and the presenter isn’t on a speakers’ bureau, my impression as a learner is that there is no potential undue influence.”

Combining the business of medicine with the science and art of medicine can create some difficult dilemmas for doctors. Some physicians, especially in specialties where incomes have

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stagnated, look at sales of products and services to boost the bottom line and, in some cases, make the difference between keeping a practice open or taking down the shingle.

Some physicians have begun to offer adjunct therapies and health-related products in order to meet patient demand for more integrated services. Others are creating “boutique practices” that charge additional fees for expedited access or highly individualized services.

Many ethicists have deemed these practices as blatant self-referral activities that are morally objectionable. Others in healthcare, including many physicians, have taken a less black-and-white view. They see the practice of health-related product sales as ethically acceptable provided the products or services are safe and physicians disclose their relationship with product providers and manufacturers, and follow basic ethical principles to avoid conflicts of interest.

The ACP's ethics manual takes the position that products sold in the physicians' office should be relevant to the patient's care and offer a clear benefit based on evidence and research. The policy further states that any markup charged should only cover the cost of making the product available, and that physicians should inform patients of their options for purchasing the products elsewhere. The ACP deems the sale of products such as cosmetic items or vitamin supplements "ethically suspect," on the grounds that such products are not directly related to patient care and could be readily obtained from other sources.

Ultimately, most ethicists concur that because physician practice itself involves an inherent overlap between medical professionalism and business operations, ethical dilemmas are common, and conflicts of interest are by their very nature difficult to anticipate and prevent.

"Physicians are struggling with a number of these issues today because of the economics of medicine and the fact that the ethical structure in this country has been based on individual providers who are self-employed or in small practice," says Dr. Neubauer. "People want practical guidance, but that's hard to provide when the environment is changing rapidly and there are societal pressures."