A patient seeks treatment for recurring back pain. A physician at an immediate care facility recommends X-ray imaging. An orthopedic physician at an outpatient clinic recommends an MRI. The pain specialist at a pain center recommends an epidural. A spine surgeon at a large health system recommends surgery. In most of these encounters (except for the spine surgeon) clinicians treat informed consent in a cursory manner. The patient is given a boilerplate informed consent document, with little conversation (again, except for the spine surgeon).

But many questions remain: Whose responsibility is it to inform the patient of the risks, benefits and alternatives of any proposed treatment? The physicians in this scenario or the healthcare organization? Moreover, should other information be shared with the patient such as outcomes data and quality data? Who should share this information? The physician, the organization or both?

Traditionally, the concept of informed consent developed within the dyad of the physician-patient relationship. In this era of great transition, we believe that this is a unique opportunity for healthcare organizations to strategically explore the importance of revising the traditional informed consent document, which should include not only the standard list of potential risks and benefits but also new information about patient quality measures, pricing/cost data, performance improvement metrics and other specific measures that may be potentially useful to the patient.

This new patient-organization framework introduces the broad concept of organizational ethics into the informed consent process that includes not only culture adaptation and trust but also the process, outcomes and character of the organization.

Beyond the ethical obligations of individual physicians, more questions come to mind: What are the new ethical and legal obligations of various healthcare organizations when obtaining informed consent? What does informed consent mean at an organizational level in a post-Affordable Care Act era? Do these healthcare entities have their own set of obligations, or should a universal approach be explored for standardization to improve patient comprehension? These questions raise a number of potential ethical obligations healthcare organizations have to their patients, providers and other stakeholders within the area of informed consent.

The new approach we propose incorporates a new patient-organization framework that not only acknowledges traditional elements of informed consent but also incorporates a new organizational obligation to address issues like population health, health outcomes and health disparities. This patient-organization framework recognizes the growing complexity of healthcare delivery and that ethical obligations of informed consent have expanded beyond the traditional physician-patient dyad. This framework is based on the premise that in the new era of health data, healthcare organizations have an opportunity to better inform patients (adding quality data, price/cost data and performance improvement metrics), improve comprehension, and achieve the ethical principles of respect for patient autonomy and disclosure.

In making our case for a new patient-organization informed consent, we refer to works that are considered seminal or by authors who are leaders in the field.
New Patient-Organization Framework

This new patient-organization framework introduces the broad concept of organizational ethics into the informed consent process that includes not only culture adaptation and trust but also the process, outcomes and character of the organization. The framework denotes "a way of acting, not a code of principles...[it] is the heart, pumping blood that perfuses the entire organization with a common sense of purpose and a shared set of values including transparency, disclosure and shared decision-making concepts," as referenced in the book No Margin, No Mission: Health Care Organizations and the Quest for Ethical Excellence (Oxford University Press, 2003).

The concept of the patient-organization framework can be defined as a continuous and collaborative approach between the patient and organization to come together around shared goals for patient care and aligning payment engagement initiatives and quality measurement, performance metrics reporting, and payment efforts around these objectives as part of the informed consent process.

Organizational Transparency

Healthcare organizations should strive for transparency throughout their functions, including the process of informed consent. Organizational transparency creates the opportunity for patient empowerment, which may enable patients to take control of their own healthcare choices, building on the traditional notion of informed consent.

One of the fundamental rights ordinary citizens should have under this new organizational informed consent framework is transparency. Healthcare organizations being transparent with price/cost data for services and procedures has the potential to drive better informed choices. Placing this type of data in the process of informed consent provides a level of fairness and equity for all patients to make more informed choices.

Just as ethics on an individual level poses questions about how we ought to act and live with others, ethics on an organizational level should be concerned with how organizations act with respect to their moral obligations toward society and their patients, as touched on in the article “Organizational Ethics in HealthCare Organizations: Proactively Managing the Ethical Climate to Ensure Organizational Integrity,” published in the September 2000 issue of HEC Forum.

Healthcare institutions have fiduciary obligations that may in some instances be the same as those of physicians, which is noted in the article “To Tell the Truth: Disclosing the Incentives and Limits of Managed Care,” in the March 1997 issue of American Journal of Managed Care.

This new patient organizational framework also focuses on the concept of disclosure and the decision-making ability of the patient, which also help shape the culture of an organization.

This new organizational approach enhances the traditional model of informed consent. The goal is to enhance the decision-making ability of the patient to truly fulfill patient self-determination. The main focus of this organizational approach to informed consent is to assist the patient in the exercise of his or her autonomy, as discussed in the article “Informed Consent in the Prescription Drug Context: The Special Case,” published in the 1986 issue (volume 61) of the Washington Law Review.

Beyond the ethical obligations of individual physicians, more questions come to mind: What are the new ethical and legal obligations of various healthcare organizations when obtaining informed consent?

Due to increasing pressures to control cost, improve quality and promote access, physicians may be influenced to disclose or not disclose based on economic cost or incentives that may be faced by the patient’s insurance plan.

The patient-organization model advances the physician-patient relationship and at the same time shares with the organization the decision-making responsibility traditionally held between the physician and patient. This new model for informed consent is not one conversation with the physician but a series of conversations with more than one healthcare professional. Because our model suggests a new innovative pathway, the communication will be centered around a
cluster of different conversations in a series of interactions.

**Shared Decision Making**

Shared decision making within the context of this model provides a robust ethical framework. Shared decision making has the potential to reduce overtreatment, improve communication and health outcomes, and reduce health disparities and health inequality. The objectives of shared decision making are to fully inform patients and their families about treatment options, including the trade-offs between risk and benefits, and to incorporate patient values and preferences into treatment decisions. Shared decision making is enhanced by improving communication, enhancing the quality of the patient experience and promoting the values of the patient. Efforts to control medical costs (inflation) are included in the patient-organization model. This model also reinforces the importance of individual autonomy. In this new light, the patient-organization model becomes important in every aspect of the patient’s treatment and departmental interactions, including financial encounters. This new model of informed consent provides the consistency that every patient deserves.

Since the ACA passed in 2010, the landscape of healthcare has changed considerably. This new patient-organization model provides a pathway for healthcare organizations to confront information inequalities that impact both health disparities and health equity.

Fiscal pressures on private and public payers have already caused far-reaching changes in the health system in the United States. This new patient-organization model provides healthcare institutions the opportunity to both re-examine the traditional concept of informed consent and take a nontraditional approach to delivering information with transparency and open disclosure to all patients. This approach creates the opportunity to better inform patients when making ethical, medical and financial decisions related to their health.

With the implementation of the ACA, patients have an even greater need to be empowered and able to weigh all areas that impact their medical care. With the current challenges of the traditional doctrine of informed consent, healthcare organizations have a unique opportunity to redesign an informed consent process that is reflective of present-day culture dynamics and healthcare markets and systematically renders information that will be useful to 21st century patients. ▲

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