new term—the learning health system (LHS)—has recently entered the vernacular of academic medicine. While advancement of knowledge has long been a central goal of academic medicine, the LHS takes this traditional perspective further to create health care systems in which … “science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience” (Institute of Medicine, 2006).

Inherent in creating LHSs is the ability to test different treatments, diagnostic modalities, or strategies for organizing care using rigorous research designs that can produce the high-quality data needed to improve clinical decision-making. Such approaches are typically more rigorous than most quality improvement evaluations and often require randomizing patients to different groups in an effort to eliminate the selection bias that impacts most treatment decisions. However, our ability to conduct these types of studies in practice is hampered by the current regulatory climate, which can create tremendous obstacles if a practice-based evaluation is considered research. Thus, if the LHS is to become a reality, a new framework for regulating low-risk practice-based research is urgently needed.

This critical agenda was recently taken up in a report released last January from the Hastings Center that challenges our current approach to regulating practice-based research. The report includes two articles by Nancy Kass, Ruth Faden, and colleagues that lay out a provocative new framework that blurs the traditional distinctions between research and practice.

The first article by Kass and Faden systematically reviews five features currently used to distinguish research from practice—that, in contrast to practice, research: 1) involves the production of generalizable knowledge; 2) requires systematic investigation; 3) offers patients less net clinical benefit and greater risk; 4) introduces burdens or risks that are otherwise not part of patients’ clinical management; and 5) uses protocols, such as randomization, to dictate which treatments or diagnostic interventions a patient receives. In a wonderful series of examples, Kass and Faden systematically identify problems with each of the distinguishing features and conclude that the features are out of date.

For example, as health care organizations move to become integrated systems of care, the development of generalizable knowledge to benefit both current and future patients will be an explicit objective of these arrangements. Thus, the intent to produce generalizable knowledge will become an unreliable way of distinguishing research from practice.

As a further example, Kass and Faden note that many clinical treatments that are widely used are of unproven value and highlight several examples of treatments (e.g., gastric freezing for peptic ulcer disease, extra cranial to intracranial bypass surgery to reduce ischemic stroke, antiarrhythmic drugs to reduce the risk of sudden death) that became widely adopted but that were later shown to be useless or harmful. Thus, Faden and Kass argue that that in many cases, research does not expose patients to greater risk than they would encounter in practice.

The second article by Kass and Faden builds on the first article and presents a new ethics framework for governing research in a LHS and rejects the basic assumption that research and clinical practice are fundamentally different endeavors. There are three key elements to the new framework. First, Kass and Faden note that there is a moral priority for learning and that health care systems and practitioners have a societal obligation to contribute to learning and improving health care. Second, this societal obligation extends to patients and is in fact justified by the principle of the “common good,” such that members of a society have a common interest in ensuring an affordable, high-quality health care system. Third, the LHS has a moral obligation to decrease inequalities in the evidence base for clinical decision-making (e.g. health needs of pregnant women) and to decrease disparities in health care outcomes. The article even touches on whether informed consent is needed for randomizing patients to test interventions, which represent “standard of care” treatments and for which there is clinical equipoise.

The Hastings Center Report also includes several excellent commentaries. One, co-authored by Harry Selker, highlights the importance of making regulatory oversight of research proportionate to the risk posed by the particular study, as continued on page 2
well as the perverse regulatory disincentives clinicians and health systems face for evaluating alternative treatments in a systematic and rigorous manner.

The Hastings Center Report is a breath of fresh air that challenges our outdated framework for regulating low-risk practice-based research to evaluate standard-of-care interventions. While the Office of Human Research Protection (OHRP) is actively examining these issues, reform of our current regulatory system will require joint advocacy by investigators, clinicians, health care leaders, and most importantly from patients who stand to benefit from the knowledge gained from such research and from the realization of LHSs.

**References**

