

Experts aim to redefine healthcare and research ethics

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In what they acknowledge as a seismic shift in the ethical foundation of medical research, practice and policy, a prominent group of interdisciplinary healthcare experts, led by bioethicists at Johns Hopkins, rejects an ethical paradigm that has guided the American system since the 1970s and calls for morally obligatory participation in a "learning healthcare system" more in step with the digital age. The group has authored a pair of articles outlining their arguments and proposal for a new ethical framework, which appear in a special report from *The Hastings Center Report*, along with seven commentaries from other experts responding to their ideas.

In one article, the authors reject the bright-line distinction between [medical research](#) and patient care that has been central to the ethical underpinnings of federal human subject research regulations for decades. They argue that it is increasingly difficult to distinguish [clinical research](#) from practice and the daily operations of healthcare organizations, and that widely held assumptions about how research differs ethically from practice may be incorrect. Specifically, the authors challenge the assumption that participation in clinical research by definition offers patients less potential benefits and puts them at greater overall risk than clinical practice, as well as the assumption that research imposes more irrelevant burdens on patients.

In today's healthcare system, the labels "research" and "practice" are poor [proxies](#) for what should be our central moral concerns, the authors argue, and no longer serve as an effective guideline for what requires

ethical oversight. They point out, for example, that over 50 percent of medical treatments are used without sufficient proof of their effectiveness, and approximately 100,000 die annually from healthcare acquired infections.

"Far too often, doctors do their best but simply don't have the information to tell them which approaches or treatments work best, and patients are suffering for that lack of knowledge," says Nancy E. Kass, deputy director for public health at the Johns Hopkins Berman Institute of Bioethics, and lead author of the article. "We're finding that patients are both underprotected from risks in medical treatment and over-protected from low-risk quality-improvement research, bringing progress to a dangerous stalemate that is costing lives," the authors write.

Instead, the authors say that healthcare should be moving toward a system in which clinical research and clinical practice are integrated, and every clinical encounter is simultaneously an opportunity to provide needed care to patients and also to learn from that to improve the care provided to future patients.

In their second article, the authors put forward a new ethical framework for the integration of research with practice in what the Institute of Medicine calls a learning healthcare system. The framework includes seven obligations, six of which fall on health professionals and institutions, and the 7th on patients:

1. Respect the rights and dignity of patients
2. Respect the clinical judgment of clinicians
3. Provide optimal care to each patient
4. Avoid imposing nonclinical risks and burdens on patients
5. Address health inequalities among populations
6. Conduct continuous learning activities that improve the quality of clinical care and health care systems

7. Contribute to the common purpose of improving the quality and value of clinical care and health care systems

The framework includes familiar tenets of both medical and research ethics, but also new obligations that the authors acknowledge "substantially revise traditional conceptions" of the roles played by health systems, providers and patients. "In addition to long-standing ethical obligations to ensure that burdens and benefits of research are fairly distributed and that patients are appropriately respected, our ethical framework directs research towards aggressive efforts to reduce or eliminate unfair inequalities in health outcomes and in the evidence base for clinical decision-making," notes Ruth R. Faden, director of the Johns Hopkins Berman Institute of Bioethics and lead author of the article outlining the framework. Among the examples of unfair inequalities the authors say should be addressed by obligation five is the scarcity of evidence for managing chronic illness in pregnant women, as compared to other adults with the same conditions. Women, and their children, would be well-served by a healthcare system that continually learns from [patient care](#).

"The framework also challenges previous thinking in research and clinical ethics by calling for an ethical obligation on the part of clinicians, administrators, payors and purchasers to conduct research to improve health care quality and value, and on patients to contribute to such research," says Faden. The authors write, "Just as health professionals and organizations have an obligation to learn, patients have an obligation to contribute to, participate in, and otherwise facilitate learning," that will improve the quality of the healthcare system.

The authors emphasize, however, that this is not a blanket obligation, regardless of risk. Some kinds of medical research, such as early testing of drugs still unapproved by the Food and Drug Administration, are not included and should always proceed only with the express, voluntary

informed consent of the patient, they say. The patient obligation is focused on research that poses no additional risk beyond what patients face in clinical care, and would also exclude research that compares different types of treatments, for example, surgery to medical management. The authors add that the framework also includes obligations to avoid imposing nonclinical risks and burdens on patients (4), and to protect their rights and interests (1).

Extraordinary opportunities for learning are lost in our current system, the authors say, because physicians and researchers face significant hurdles in capturing the rich information generated from thousands of daily medical encounters with patients due to overly burdensome oversight and consent rules. The new framework is intended to help reduce these hurdles.

The authors write that they expect their articles will spark debate, and hope they will move the transformation to a learning [healthcare system](#) forward, both in its ethical underpinnings and in practice. They write, "We claim no more than a start on a subject that merits extensive investigation, and we welcome suggestions and commentary moving forward... We are in the early days of a progressive realization of a lofty aspirational goal, but given the preventable harm, waste, and uncertainty about clinical effectiveness in health care, efforts to accelerate learning should be given high priority."

More information: Ethical Oversight of Learning Health Care Systems, Hastings Center Report Special Report 43, no. 1 (2013) onlinelibrary.wiley.com/doi/10.1111/hast.12143

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