



An Ethics Framework for a Learning Health Care System: *A Departure from Traditional Research Ethics and Clinical Ethics*

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Calls are increasing for American health care to be organized as a learning health care system,¹ defined by the Institute of Medicine as a health care system “in which knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care.”² We applaud this conception, and in this paper, we put forward a new ethics framework for it. No such framework has previously been articulated. The goals of our framework are twofold: to support the transformation to a learning health care system and to help ensure that learning activities carried out within such a system are conducted in an ethically acceptable fashion.

A moral framework for a learning health care system will depart in important respects from contemporary conceptions of clinical and research ethics. The dominant paradigm in research ethics and in federal regulations has relied on a sharp distinction between research and practice—a segregation model that dates to the influential publications of the National Commission for the Protection of Human Subjects in the 1970s.³ The learning health care system, by contrast, proposes that it is acceptable and indeed essential to integrate research and practice.⁴ From this perspective, the dominant ethical paradigm from the 1970s to the present time is anti-

thetical to and problematic for the learning health care system, at a time when clinical practice is far from optimal and learning to improve care is sorely needed. Several hundred thousand people die needlessly each year from medical mistakes.⁵ There is reason to believe that adult patients receive only approximately 50 percent of recommended therapies,⁶ and that up to 30 percent of health care spending is wasted.⁷ The need to improve health care is urgent, yet the current ethics paradigm may hinder improvement. For example, the expansion of one of the most successful quality improvement interventions ever—saving thousands of lives by preventing central line-associated bloodstream infections in intensive care units—was almost halted due to concerns about research ethics oversight.⁸ But few have come forward to express concerns and oversight for the thirty thousand or so people who will die unnecessarily each year in the United States from this type of infection.

Quality improvement and comparative effectiveness research are emblematic of the kinds of ongoing learning activities that a learning health care system is designed to promote. As we argue in the first article in this supplement to the *Hastings Center Report*, quality improvement and comparative effectiveness research bring into sharp relief the problems with the criteria traditionally used to distinguish research and practice. The fuzziness of the distinction, coupled with the oversight burdens that are required of research but not of practice, creates dubious incentives to redesign quality improvement and comparative effectiveness activities in ways that minimize the likelihood that they will be classified as re-

Ruth R. Faden, Nancy E. Kass, Steven N. Goodman, Peter Pronovost, Sean Tunis, and Tom L. Beauchamp, “An Ethics Framework for a Learning Health Care System: A Departure from Traditional Research Ethics and Clinical Ethics,” *Ethical Oversight of Learning Health Care Systems, Hastings Center Report Special Report* 43, no. 1 (2013): S16-S27. DOI: 10.1002/hast.134

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search, even at the cost of their rigor, utility, dissemination, or value.⁹ There have been recent attempts to modify the dominant paradigm to accommodate at least some kinds of quality improvement and comparative effectiveness research,¹⁰ but these efforts are limited in reach and impact. Going forward, the fundamental structure and assumptions of the traditional segregation model rest too heavily on an unjustifiably sharp distinction between research and practice. The traditional model now stands to frustrate integrated, real-time learning, which is at the heart of where our health care system should be headed.

The framework we propose in this paper rejects the assumption that clinical research and clinical practice are, from an ethics standpoint, fundamentally different enterprises. It departs significantly from today's research ethics and clinical ethics paradigms in two key respects. First, the framework sets a moral priority on learning. It includes a specific, novel obligation on health professionals and health care institutions to be active contributors to learning in health care. We argue that a similar obligation extends to patients, who have traditionally not been conceived in research ethics as having a duty to contribute to the ongoing learning that is integrated with the health care they receive. Second, the framework includes an obligation to address problems of unjust inequalities in health care—an obligation that reaches beyond the demands of justice in traditional and contemporary codes of research and clinical ethics. Our view is that the time has come for these changes to be recognized as central moral obligations in health care.

We begin by briefly stating the main arguments that morally justify the transformation to a learning health care system. The justification builds upon and complements the arguments in favor of learning health care that have been provided elsewhere.¹¹ We then describe what we mean by a learning activity and the structure of what we call the learning health care system ethics framework. This description is followed by an analysis of each of the framework's seven major elements. Each element is stated as an independent obligation. We consider how each element is similar to or different from requirements prevalent in contemporary research ethics and clinical ethics. We conclude with a discussion of some of the next steps needed to explicate how the framework can be used to guide the ethics of learning in a learning health care system.

A Moral Justification of the Learning Health Care System

The traditional principles that provide the moral grounding for human subjects protection in the United States became cemented as the cornerstones of research ethics in the 1970s¹² during a period of intense societal focus on civil rights and on egregious violations of rights that occurred in highly publicized research scandals. Since the 1970s, the dominant concern has been to protect patients and other subjects from risk, abuse, and unjust distributions of the burdens of research.

An ethical imperative that was less central in bioethics in the 1970s—namely, the establishment of a just health care system—provides an important moral reason, generally overlooked, for a rapid transformation to a learning health care system. There is considerable disagreement about the design of a just health care system and how health care should be organized and financed to achieve it, but arguably there is broad agreement that, at minimum, a just system is one in which present and future generations are able to access adequate health care services without the imposition of undue financial burdens on patients and their families. The obstacles to securing a just health care system, so defined, are complex and include cultural, economic, and political as well as scientific and public health challenges. That said, securing just health care requires a constantly updated body of evidence about the effectiveness and value of health care interventions and of alternative ways to deliver and finance health care. A learning health care system is critical to the efficient and systematic collection and dissemination of this evidence, and we think it is a necessary condition of achieving the goal of creating and maintaining a just health care system.

The societal goal of a just health care system provides only one of three independent and equally important ethical justifications for the transition to learning health care systems. The other two are the goals of high-quality health care and economic well-being. By “high-quality health care” we mean, at minimum, technically competent health care that is based on the strongest clinical evidence and is delivered with the highest achievable patient safety. By “economic well-being” we mean, at minimum, a society in which current and future generations have the economic resources necessary to live a decent human life over the course of the life span. The im-

Table I.
Learning Health Care System Ethics Framework

<i>Obligation</i>	<i>Parties Bearing the Obligation</i>	<i>Synopsis of the Obligation for Learning Activities</i>
Respect the rights and dignity of patients¹	<ul style="list-style-type: none"> • researchers • clinicians • health care systems administrators • payers • purchasers 	<ul style="list-style-type: none"> • Assess the impact of a learning activity on the rights, respect, and dignity of patients • Assess whether a learning activity limits patient choice, as well as the value to patients of any choices so affected
Respect clinician judgments	<ul style="list-style-type: none"> • researchers • health care systems administrators • payers • purchasers 	<ul style="list-style-type: none"> • Assess the impact of a learning activity on the exercise of clinician judgment • Assess the importance of any restriction on the exercise of clinician judgment for the health and autonomy interests of patients
Provide optimal clinical care to each patient	<ul style="list-style-type: none"> • researchers² • clinicians • health care systems administrators • payers • purchasers 	<ul style="list-style-type: none"> • Assess the expected net clinical benefit for patients affected by the learning activity, compared to the net clinical benefit they likely would have experienced if their clinical care had not been affected by the learning activity
Avoid imposing nonclinical risks and burdens on patients	<ul style="list-style-type: none"> • researchers • clinicians • health care systems administrators • payers • purchasers 	<ul style="list-style-type: none"> • Assess the nonclinical risks and burdens to patients affected by a learning activity, compared to the nonclinical risks and burdens they likely would have experienced if they had not been affected by the learning activity
Address health inequalities	<ul style="list-style-type: none"> • researchers • clinicians • health care systems administrators • payers • purchasers 	<ul style="list-style-type: none"> • Assess whether the risks and burdens of a learning activity will fall disproportionately on patients who are already disadvantaged • Assess whether the learning activity will disproportionately benefit patients who are already socially and economically advantaged • Assess whether a learning activity will help advance the goal of reducing unjust inequalities in health and health care or can be designed to do so
Conduct continuous learning activities that improve the quality of clinical care and health care systems	<ul style="list-style-type: none"> • researchers • clinicians • health care systems administrators • payers • purchasers 	<ul style="list-style-type: none"> • Conduct and contribute to learning activities as a matter of role-specific, professional responsibility • Assess the extent to which a learning activity will likely contribute to the quality, fairness, or value of health care services and systems by assessing the soundness of the learning activity's objectives, design, and plans for dissemination and implementation
Contribute to the common purpose of improving the quality and value of clinical care and health care systems	<ul style="list-style-type: none"> • patients 	<ul style="list-style-type: none"> • Participate in learning activities that are consonant with other obligations in the framework intended to respect the rights and interests of patients; participate in activities deemed acceptable to go forward without patients' express informed consent • Consider participation in learning activities that because of their impact on the framework's other obligations cannot ethically go forward without express informed consent

¹This framework has implications for family members, loved ones, and surrogates of patients. Both the first and the seventh obligation extend to family members, loved ones, and surrogates when patients are children or adults whose competence is permanently or temporarily compromised and when adult patients want or need their loved ones to be involved in their care.

²If researchers do not otherwise have clinical duties to the patients who are affected by a learning activity, then they do not shoulder an obligation to provide patients with optimal clinical care.

We should assess both whether a learning activity unduly limits the choices of patients and the value of those choices to patients. Many decisions in health care are not likely to engage values of central importance to the patient.

portance of efficient and real-time learning to the securing of quality health care is indisputable. The relationship between learning in health care and economic well-being is perhaps less apparent but is arguably as important. Broad agreement exists that the pace at which U.S. health care costs continue to escalate constitutes a serious threat to the economic prospects of the country, individuals, and families; continuous, efficient learning in health care is essential (though not sufficient) to the slowing of this pace and thus to economic well-being.¹³

The goals of just health care, high-quality health care, and economic well-being provide independent moral reasons for the transformation of current health care organizations into learning health care systems. These goals underlie our aim in this paper to present a framework of moral obligations that both integrates and alters some basic ideas in our current research ethics and clinical ethics paradigms. For some readers, the need to improve health care quality may be the most important reason for the transition to a learning health care system, and possibly even the only justificatory reason they accept. This rationale is narrower than our three-reasons approach, but in no way undermines the moral imperative to move to learning health care systems. The improvement of health care quality is a sufficient reason alone. So, too, is a commitment to ensuring economic well-being.

What Counts as a Learning Activity?

A learning activity is one that both 1) involves the delivery of health care services or uses individual health information, and 2) has a targeted objective of learning how to improve clinical practice or the value, quality, or efficiency of the systems, institutions, and modalities through which health care services are provided. All such activities are learning activities, even if they have typically been categorized as clinical research, clinical trials, comparative effectiveness research, quality improvement research, quality improvement practice, patient safety practice, health care operations, quality assurance, or evidence-based management. We do not contest these labels or classification schemes, but they also do not control or influence our analysis. For our purposes, they are all “learning activities.”

Health care services include a wide range of interventions and interactions in which professionals are involved with patients, sometimes over long periods of time. They include

encounters between patients and health care professionals in the traditional settings in which clinical services are provided, as well as in settings such as patients’ homes, pharmacies, and the workplace, and they may occur virtually through telemedicine or other Internet-based modalities. Health information includes any information that relates to an individual’s physical or mental health, the health care services provided to an individual, or the payment for an individual’s health care, whether in the past, present, or future.¹⁴

The Basic Structure of the Framework

The framework we propose consists of seven obligations: 1) to respect the rights and dignity of patients; 2) to respect the clinical judgment of clinicians; 3) to provide optimal care to each patient; 4) to avoid imposing nonclinical risks and burdens on patients; 5) to reduce health inequalities among populations; 6) to conduct responsible activities that foster learning from clinical care and clinical information; and 7) to contribute to the common purpose of improving the quality and value of clinical care and health care systems.

Respecting patient rights and dignity and avoiding nonclinical risks (obligations 1 and 4) appear in most contemporary discussions of research ethics. Respecting the judgment of clinicians and providing patients with optimal clinical care (obligations 2 and 3) are presuppositions of traditional medical ethics—as, for example, in the influential catalogue of norms in Thomas Percival’s classic volume, *Medical Ethics*.¹⁵ Variations of these four obligations are prominent in contemporary discussions of medical professionalism,¹⁶ and they remain relevant in our framework. However, we also give each an interpretation not found in codified principles of either clinical ethics or research ethics.

Obligations 5, 6, and 7 are specific to the learning health care system context. These three obligations substantially revise traditional conceptions of the moral foundations of research ethics and clinical ethics. Obligations 5 and 6 have more than one obligation-bearer, as presented in Table 1, with the obligations falling on clinicians, investigators, health care institutions, those responsible for institutional policies and practices, payers, and purchasers. Patients are the obligation-bearers in obligation 7, which proposes to sharply reform current rules and guidelines. This obligation placed on patients to contribute, under limited and appropriate condi-

tions, to learning that is integrated with their clinical care is not present in conventional accounts of either clinical ethics or research ethics, where the assumption is that no such obligation exists.

All seven obligations are relevant to judgments about the ways in which a learning activity can negatively or positively affect the rights or interests of patients and professionals. The term “rights” refers to justified claims to something that individuals and groups can legitimately assert against other individuals or groups. The associated term “interests” refers to that which is in an individual’s interest—that is, that which supports an individual’s well-being or welfare in a given circumstance. We use the term “risk” to refer exclusively to a risk of “harm,” meaning a thwarting, defeating, or setting back of an individual’s interests.¹⁷

Seven Fundamental Obligations

Each of the seven obligations in the framework constitutes a necessary condition, within a learning health care system, of an adequate ethics. In the absence of any one of these obligations, the framework would lose a basic norm, rendering the framework deficient. However, we do not claim that this set of obligations establishes a set of sufficient conditions in a comprehensive ethical framework. Future work can be expected to specify these abstract rules to provide more granular guidance for institutions and their specific contexts and to perhaps add additional general obligations.

The seven norms presented below have some overlapping content, but no one norm can be reduced to one or more of the others. They are not morally weighted or placed in a hierarchical order of importance. Questions of weight and priority can be assessed only in specific contexts. When these norms come into conflict in particular learning activities, the goal will be to show either that one norm is of overriding importance in that context or that at least some demands of each of the conflicting norms can be satisfied, whereas others cannot.

1) The obligation to respect patients. Moral obligations to respect the rights and dignity of persons are not controversial in either clinical ethics or research ethics.¹⁸ Examples of respecting rights include obtaining informed consent, soliciting and accepting advance directives, protecting the confidentiality of health information, and evaluating the effectiveness of health care in terms of outcomes that matter to patients. Respecting the dignity of patients requires health professionals to express respectful attitudes and to treat patients as having an inherent moral worth by, for example, helping patients understand what is happening to them and following the lead of patients in involving their families and friends in their care.

Among the rights most discussed in research ethics and clinical ethics is the right to have one’s autonomy respected.

The obligation to respect patient autonomy is also central to the framework we are proposing, but unlike some bioethics literature, the framework does not give it undue deference or overriding importance.¹⁹ Respecting autonomy is primarily about allowing persons to shape the basic course of their lives in line with their values and independent of the control of others.²⁰ Not all health care decisions are likely to be attached to a significant autonomy interest of individual patients, and deference of the wrong sort can constitute a moral failure to take adequate care of patients rather than an instance of showing respect.

In interpreting the obligation to respect autonomy in learning health care contexts, we should assess both whether a learning activity unduly limits the choices of patients and the value of those choices to patients. Many decisions in health care—such as how often simple laboratory tests should be repeated during a hospitalization or whether medications should be dispensed by one qualified professional or another—are not likely to engage values of central importance to the patient.²¹ Learning activities that relate to such decisions can be undertaken by health professionals and institutional officials without a violation of obligations to respect the rights or dignity of patients.

2) The obligation to respect clinician judgment. The importance of clinician judgment to professional practice is well established, although what is meant by clinician judgment is not always clear. We use the term “judgment” broadly to mean the clinician’s considered beliefs about how best to care for a patient in light of multiple considerations and influences, including personal professional experience, the experience of colleagues and mentors, scientific evidence, and the clinician’s understanding of the patient’s values and priorities. Respect for clinicians’ judgments is justified for two reasons. First, the exercise of clinical judgment can further the health interests of patients in achieving the best clinical outcome.²² Second, the exercise of clinical judgment can advance the autonomy interests of patients because clinicians are often well positioned to ascertain and be responsive to their values and preferences.

Not all constraints on the behavior of clinicians—such as requirements to write notes for a supervisor or to use a uniform method for dosing orders—interfere with the exercise of clinician judgment. Some other constraints interfere with the exercise of clinician judgment, but to varying degrees. For example, formularies requiring physicians to prescribe only one branded drug among several in the same class may have little if any negative impact on the health and autonomy interests of patients that respect for clinician judgment is intended to serve. Learning activities that impose constraints of these types would be compatible with the obligation to respect clinician judgment.

When learning activities target areas in which there is clinical uncertainty about best practices or limited empirical evidence, the importance of respecting clinician judgment is weakened.

One problem with the obligation to respect clinician judgments is that even the most well-intentioned judgments of clinicians can be subject to some form of bias.²³ A key precept of evidence-based medicine is that clinician judgment may not result in the best health outcomes for patients, especially when there is an absence of good empirical evidence or that evidence does not factor in the forming of the judgment. Evaluating the strength of the obligation to respect clinician judgment usually entails a contextual assessment of the likely impact of any proposed restriction on the exercise of clinician judgment on patients' health or autonomy interests. When learning activities target areas in which there is clinical uncertainty about best practices or limited empirical evidence, the likelihood that unrestricted clinician judgment will advance the health interests of patients is lessened, and the importance of respecting clinician judgment is weakened. For example, for most patients, there is currently little empirical evidence to support a clinician's judgment that a particular first-line hypertension drug is better than another. The obligation to respect clinician judgment in this context is not as stringent as in a case where clinician judgment is based on more robust evidence or is responsive to patient preferences for different therapeutic options.

3) *The obligation to provide optimal care to each patient.* Obligations to promote the welfare of others take on specific forms in health care, usually formulated as role obligations. Professional codes underscore the moral responsibilities of professionals to advance the welfare interests of each patient by providing the patient with optimal care aimed at securing the best possible clinical outcome. "Clinical outcome" encompasses the interests patients have in the promotion, preservation, and restoration of their health and the mitigation of pain, suffering, and disability. During the course of clinical care, clinical risks of setbacks to the health interests of patients are often present. These risks are morally justified if they are outweighed by the prospect of corresponding clinical benefits. Accordingly, clinical care can be ethically acceptable when significant risks are present, as long as the potential or expected benefit to the patient justifies the risk.

A central moral consideration in assessing the ethical acceptability of a learning activity is how the expected net clinical benefit for the patients affected by a learning activity compares to the net benefit they likely would have experi-

enced if their care had not been affected by that activity. In assessing net clinical benefit, the risks in routine clinical practice should be considered. Some learning activities are likely to increase the prospects for net clinical benefit, whereas others are likely to decrease it. An activity designed to evaluate the impact of a computer-generated prompt to clinicians to double-check medication dosage may itself have a positive impact on the net clinical benefits for patients; it may reduce the risk that they will be harmed by a medical error. By contrast, depending on the context, a randomized clinical trial of a first-in-class medication may decrease patients' prospects for net clinical benefit relative to what would be expected if these patients receive approved medical therapies. Other learning activities—such as a prospective observational study that relies only on electronic health data to compare widely used interventions—are likely to have no appreciable effects on net clinical benefit. Accordingly, the impact of a learning activity on net clinical benefit is specific to the particulars of the activity and the related clinical context, but it is morally essential that such assessments be made in a learning health care context.

4) *The obligation to avoid imposing nonclinical risks and burdens.* Health care focuses on the health-related interests of patients and the reduction of risks of health-related harms, but obligations to avoid inflicting other kinds of harm and burden also apply in health care. Clinical care and clinical information can be provided or used in ways that affect patients' interests in financial well-being, social standing and reputation, employment and insurance opportunities, dignity, privacy, and the joy of spending time with family and loved ones.

The impact of a learning activity in imposing nonclinical risks and burdens—in comparison to the nonclinical risks and burdens that the patients could be expected to experience if their clinical care did not involve the learning activity—is a moral consideration. For example, the risk that health information will be disclosed inappropriately sometimes increases as a result of a learning activity, and such disclosures can be monitored and reduced through security protections. Learning activities also may impose burdens beyond those needed for patients' usual clinical care, such as extra visits to clinical facilities.

5) *The obligation to address unjust inequalities.* Our framework is rooted in a broader conception of obligations of justice than the conception that dominates traditional research ethics. Fundamental to traditional formulations and to the regulation of research are moral requirements that subject selection be fair and that the distribution of research benefits and burdens be just.²⁴ Our framework supports the commitment to these injunctions, which are historically rooted in concerns about the abuse of disadvantaged or vulnerable subjects in research. However, these injunctions carve out only a piece of the territory of justice that needs to be considered in the ethics of a learning health care system.

In agreement with the traditional conception, our framework sets a presumptive bar against learning activities whose potential negative effects—including imposition of non-clinical burdens or the worsening of prospects for net clinical benefit—fall disproportionately on socially and economically disadvantaged patients or groups of patients. This bar protects many individuals who are homeless, poorly educated, belong to groups that have been subject to historical and continuing prejudicial treatment, or lack access to health care and physicians. Also in need of monitoring are learning activities whose positive outcomes will disproportionately benefit patients who are already socially and economically advantaged—for example, activities that rely on access to the Internet in the home. This obligation requires those who propose learning activities to consider whether the activity can be carried out in such a way that its benefits extend to the less privileged.

In ways more expansive than traditional conceptions, the learning health care system ethics framework also imposes an affirmative obligation to direct learning activities toward aggressive efforts to reduce or eliminate unfair or unacceptable inequalities in the evidence base available for clinical decision-making, in health care outcomes, and in the respectfulness with which health care is delivered. For example, it is widely acknowledged that pregnant women often respond to medications differently than other adults, but the health needs of pregnant women are rarely the focus of clinical investigation because of concerns about the impact of the medications on the fetus. A learning health care system is well positioned to identify—and should mount—ethically acceptable learning activities to address what some have identified as unjust paucity of evidence about the management of chronic illness in pregnant women.²⁵

Learning activities also should target disparities in clinical outcomes associated with widening educational differences in adult mortality from such health conditions as lung cancer and heart disease.²⁶ Similarly, learning activities should find strategies to reduce the disrespectful ways in which patients in sickle-cell crisis are sometimes treated when they seek pain relief in emergency rooms. Unlike other patients presenting in severe pain, these patients, who are largely young African Americans and thus subject to unjust racial stereotyping, are

often treated with suspicion by clinical staff, who view them not as people suffering from a dreadful disease but as drug users hoping to manipulate the system in search of opiates.²⁷

Although reasonable people often disagree about precisely which inequalities are unjust and for what reasons,²⁸ the narrowing of inequalities and the elimination of discrimination in care between minority and majority patients, economically impoverished and economically secure patients, and poorly educated and well-educated patients is a national priority in the United States and in many other countries.²⁹ The learning health care ethics framework requires that learning activities be assessed to determine whether they perpetuate or exacerbate unjust inequalities and to determine whether they can be structured to advance the goal of reducing or eliminating inequalities and discrimination in health care. This role has not traditionally been at the forefront of the list of obligations of health care institutions, where these problems of unjust inequalities have been widely overlooked.

6) *The obligation to conduct continuous learning activities that improve the quality of clinical care and health care systems.* The third obligation of our framework—to provide each patient optimal clinical care—has been linked to clinical ethics requirements that clinicians stay current in their knowledge and their skills.³⁰ Until recently, there has been little discussion of the need to augment this obligation with an affirmative responsibility on the part of clinicians to contribute to that knowledge base.³¹ This sixth obligation makes contribution to learning morally obligatory. It also extends its reach beyond health care professionals to institutions, payers, and purchasers of health care. We envision an unprecedented transformation of responsibilities in a learning health care system that applies to physicians in private practice, pharmaceutical companies, private hospitals, and so on. Because health care professionals, officials of health care institutions, and purchasers of health care have unique access to and control over clinical care and health information, they are uniquely positioned to seek, conduct, and contribute to learning activities that can advance health care quality, economic viability, and a just health care system. No other individuals, professionals, or institutions in society have such access or control.

The learning health care system ethics framework makes this sixth obligation foundational in the structuring of health professions and health care institutions. The obligation requires that every practitioner and institution accept a responsibility to feed information into the system that increases our knowledge. Each learning activity to be conducted within the system must be individually assessed for the extent to which it holds out the prospect of contributing to the improvement of health care services and systems. This assessment should include an evaluation of the soundness of the learning activity's objectives, design, and plans for implementation or dissemination. Learning activities today may improve only the

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specific health care settings in which a learning activity takes place, with only some activities and new information being transportable to a wider body of health care institutions. This current limitation will gradually be transformed into a vast array of interconnected learning activities.

7) *The obligation of patients to contribute to the common purpose of improving the quality and value of clinical care and the health care system.* Traditional codes, declarations, and government reports in research ethics and clinical ethics have never emphasized obligations of patients to contribute to knowledge as research subjects. These traditional presumptions need to change. Just as health professionals and organizations have an obligation to learn, patients have an obligation to contribute to, participate in, and otherwise facilitate learning.

This obligation is justified by what we call a norm of common purpose. This norm of *common purpose* is similar to what John Rawls calls the principle of the *common good*, a principle presiding over matters that affect the interests of everyone.³² The common interest of members of a society in the health care system is that it be positioned to provide each person in the society with quality health care at a cost compatible with individual and societal economic well-being. We also have a common interest in supporting just institutions, including activities that reduce the unjust inequalities that were mentioned in obligation 5.

Securing these common interests is a shared social purpose that we cannot as individuals achieve. Our goals cannot be reached efficiently without near-universal participation in learning activities, through which patients benefit from the past contributions of other patients whose information has helped advance knowledge and improve care. Patients cannot discharge this obligation merely by paying a fee for the health care service they receive or by contributing to society through taxation or charitable contributions. No amount of money paid for health care services substitutes for direct participation in and contribution to learning activities. The knowledge necessary to secure a high-quality and just health care system cannot be obtained from information limited to a bounded number of patients at discrete points in time. A learning health care system must have continuous access to information about as many patients as possible to be efficient, affordable, fair, and of highest quality.

A related justification for obligation 7 is the reciprocal obligation that arises among strangers who occupy the role of patient over time. The philosopher David Hume expresses the general form of this duty of beneficence as follows: “All our obligations to do good to society seem to imply something reciprocal. I receive the benefits of society, and therefore ought to promote its interest.”³³ In our framework, the discharge of obligations of reciprocity occurs through an established practice of making an appropriate and proportional return—returning benefit with proportional benefit, with all alike sharing, as a matter of moral obligation, the burdens necessary to produce these benefits.

In proposing that patients have an obligation to contribute to the common purpose of improving health care through learning, we are not proposing that patients have an affirmative moral obligation to participate in all learning activities regardless of the degree of additional risk or burden they may impose. Different learning activities will have differential effects on the rights and interests of patients and therefore will have different implications for patients’ obligations to participate in them. The first four obligations of this framework are intended to protect these rights and interests in the assessment of the overall ethical acceptability of particular learning activities. For example, some learning activities, such as randomized clinical trials of investigational new devices, would not be obligatory because of the potential to fail in meeting obligations 1 through 4. If this type of learning activity is otherwise ethically acceptable, however, then patients might *choose* to participate in it, though they should be informed and understand that they are under no obligation to do so. By contrast, other learning activities—such as participation in a registry, reviews of deidentified medical records, and being interviewed by health care staff to better improve the patient care experience—are likely to be instances in which patients do have an obligation to participate, assuming that the activities have a reasonable likelihood of improving health care quality and that appropriate data security protections are in place. These conditions are probably met currently in integrated health care systems that have invested in secure electronic health records and have mechanisms in place to adjust local norms of care in direct response to the results of learning activities.³⁴

The obligation of patients to contribute to health care learning is compatible with duties to inform patients about

learning activities and to solicit their express consent for some learning activities, as appropriate. The first obligation in our framework requires, as a matter of respect, that health care institutions have numerous and varied policies and practices in place to inform patients about the institution's commitment to learning and about the specific learning activities that are currently underway and how they are being conducted. Activities such as randomized, controlled trials of an investigational new device could proceed only with patients' express, affirmative agreement, obtained through a valid informed consent process.

As with the first obligation above, the obligation to contribute to learning can extend to family members, loved ones, and surrogates of patients, particularly when patients are children or adults whose competence is permanently or temporarily compromised. Whenever loved ones are intimately involved in the care of the patient, they may have information or insight critical to learning about and improving health care interventions and processes. For patients lacking cognitive or decisional capacities, loved ones and other surrogates can play a vital role in the ethics framework by representing and protecting patients' interests of during learning activities.

It has several times been asked in the bioethics literature whether there is a duty to serve as a research subject. Some have answered the question affirmatively. Their reasons have been premised on a conception of duties to participate reciprocally in a system that produces public goods from which we all benefit and in which no one should, in this respect, be a free rider.³⁵ In certain circumstances, even compulsory participation has been proposed.³⁶ Although similar justice-oriented grounds are central in some of our arguments, we are proposing a more pervasive level of participation, and participation of a different type, than previous writers have recommended. We make it a condition of participating in a learning health care system as a patient that one also participates in the learning activities that are integrated, on an ongoing basis, with the clinical care patients receive.³⁷ The scope of participation that we are proposing is far more extensive and notably different from than that proposed by previous writers on duties to participate in research.

Going Forward with the Learning Health Care System Ethics Framework

The framework we have proposed for a learning health care system departs significantly from previous frameworks in research and clinical ethics. Its most distinctive features are twofold. First, the framework eschews the moral relevance of the traditional distinction between research and practice in a learning health care environment, focusing attention instead on the moral obligations that should govern an integrated learning health care system. Second, the framework sets a moral presumption in favor of learning, in which health pro-

fessionals and institutions have an affirmative obligation to conduct learning activities and patients have an affirmative obligation to contribute to these activities. This presumption is grounded in the claims that all parties benefit from this arrangement and that the societal goals of health care quality, just health care, and economic well-being require continuous learning through the integration of research and practice.

This framework will help facilitate the transformation to a learning health care system. Going forward, the next step will be to specify the framework's implications for oversight policies and practices, including prior review and informed consent, and to determine precisely how the framework will interact with the current human subjects regulations and institutional review board system. Given that our framework rejects the moral relevance of the traditional distinction between research and practice in a learning health care system, different operational criteria for determining which activities should be subject to oversight policies, based on the seven moral obligations, will need watchful development. For example, future work will need to use multiple criteria to determine which activities require express prospective consent and which may be addressed by routine disclosures. Critical to this work is canvassing the views of patients and other stakeholders—an effort that is already under way.³⁸ Although the hard work of specifying the policies and practices needed to implement the framework is just beginning, we close with a few preliminary observations—first, about the implications of the framework for clinical practice, and second, about the operationalization of the first and seventh obligations.

As we argue in the first article in this set, the underprotection of patients from unjustified and often preventable harms and burdens in clinical practice is a profoundly serious moral problem. We are not proposing, nor do we think it correct, that the solution to the underprotection problem is simply to expand the current review system for research. Multiple conditions and factors contribute to the underprotection problem, and a complex set of strategies will be needed to address the problem effectively. The learning health care ethics framework is intended to be one part of the solution. First, the framework makes obligatory the kinds of learning that are necessary to reduce the harms that occur in clinical environments and resolve the uncertainties that exist around many clinical practices. Second, the framework makes such learning easier to conduct; by reducing the overprotection of patients from learning activities that do not undermine their interests or rights, it facilitates learning that can help address the underprotection of patients in clinical practice. Put slightly differently, insofar as contemporary research ethics and oversight interfere with learning activities that could reduce errors and improve clinical effectiveness, the overprotection that results is itself a source of harm to patients' interests.

Health care institutions and clinicians are constantly adopting new practices, ranging from platforms to support

clinical decision-making built on electronic health systems to minimally invasive and robotic surgery. These innovations are often introduced without systematic assessment of their impact, perhaps to avoid crossing the unwelcome and curious divide between practice and research. Our framework makes this distinction irrelevant to questions of oversight and provides reasons why health care institutions and professionals are obligated to accompany the introduction of such innovations—as well as practices that have never been rigorously evaluated—with a commitment to systematically learn about their effects on clinical outcomes, health care value, patients' experience, and health disparities.

We envision that a learning health care system will adopt an array of policies and practices that provide a moral link between the first obligation—to respect the rights and dignity of patients—with the seventh obligation—that patients contribute to the common purpose of improving the quality of clinical care and the health care system. For example, the learning health care system would disclose to patients in multiple ways and at various times that learning occurs constantly throughout the health care system, and that the products of such learning are constantly updated and integrated into the system of care. Concrete examples would be provided of how care has been improved as a result of learning. Such disclosure serves to underscore to patients the system's moral commitment to continuous learning, the relationship of that learning to the quality of care they will receive, and the system's commitment to ensuring that patients are aware of continuing learning activities and their risks and benefits. Disclosure procedures might include information provided at initial interviews or at enrollment, in postings in waiting rooms, and in newsletters and Web sites. The best ways to communicate with patients must be identified and evaluated, and these approaches to disclosure should be shared with small hospitals and practices without the resources to do so on their own.

The health care system would likewise inform patients in routine and systematic ways of the policies that are in place to provide ethical oversight of learning activities, as well as how the confidentiality of their medical information will be maintained, how privacy is insured, how information is transmitted to other health care institutions, and the like. There would also be transparency in the conduct of learning activities. Transparency might be achieved by, for example, listing the steady flow of learning activities on system Web sites (and on paper, if requested) and by accountability to the public and to patients regarding what is learned in these activities, including whether and how a learning activity has improved clinical practice. In addition, a learning health care system would publicize to patients that, while they might not be informed routinely about each learning activity—since many have little, if any, effect on patients' interests or rights—they will be adequately informed, and their consent sought, when-

ever a learning activity might have a negative impact on the quality of care or impose burdens above and beyond what they would otherwise experience.

Finally, we appreciate that the learning health care system ethics framework we have proposed will be criticized as a premature and overly extensive reshaping of traditional research ethics and clinical ethics. Others may think we propose too little. We claim no more than a start on a subject that merits extensive investigation, and we welcome suggestions and commentary moving forward. The transformation to a learning health care system is still in its infancy. 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. Now is a good time to lay the ethical foundations of a learning health care system and to begin work on its specific moral commitments.

Acknowledgments

This work was supported by grant RC1RR028876 from the National Institutes of Health, National Center for Research Resources. The content is solely the responsibility of the authors and does not represent the official views of the NCCR or the NIH. We are indebted to other members of our research team—Joe Ali, Dan O'Connor, Yashar Saghai, and Danielle Whicher—for their input on the thinking that went into this paper. We are also indebted to Ethan Bosch, Carolyn Clancy, Frank Davidoff, Richard Platt, Joseph Selby, and Arnold Milstein for their thoughtful and very helpful responses to the paper; to a group of patient advocates who generously gave of their time to critique and improve our framework; and to Jeremy Sugarman and other colleagues at the Berman Institute of Bioethics for their insightful feedback. We also thank Ishan Dasgupta, Judie Hyun, and Kelsey Perkins for their able research assistance and help in preparing this manuscript for submission.

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