

POLICY ANALYSIS

Ethics and Learning Health Care: The Essential roles of engagement, transparency, and accountability

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Abstract

Extraordinary innovation in medicine promises vast improvements to the health of individuals and communities. Yet it is a lost opportunity that data from most medical care is never aggregated or analyzed. Even when data are aggregated and analyzed, most of this “learning” is never translated into improved practice. The Learning Health Care System (LHCS) is a response to both of these challenges. Ethically, the LHCS relies on a foundational understanding between patients and their health systems in which patients endorse the use of their data for ongoing learning, and health systems commit to improving care based on what is learned. We have outlined elsewhere a set of seven ethical obligations for Learning Health Care, including the obligation to respect the rights and dignity of patients. In this paper, we suggest that three specific respect-promoting actions are morally required in a LHCS: engagement with patients about ongoing learning activities, transparency with patients about ongoing learning activities, and accountability in implementing what is learned.

KEYWORDS

ethics, learning health care, engagement, transparency, accountability

1 | INTRODUCTION

Extraordinary innovation in medicine promises vast improvements to the health of individuals and communities. Yet two challenges stand in the way of fulfilling this promise. First, data from most medical care is never aggregated or analyzed, creating a lost opportunity to learn from care previously delivered.¹ Second, there is a significant shortfall between what is learned from these data and what is translated into practice.^{2,3} The Learning Health Care System (LHCS) is a response to both of these challenges. In an LHCS, continuous feedback loops ensure that “new knowledge [is] captured as an integral by-product of the care experience” and “best practices [are] seamlessly embedded in the care process.”⁴ Healthcare institutions are increasingly interested in becoming LHCS. However, unless *both* knowledge generation *and* knowledge translation are in place, the LHCS stands on shaky moral ground.

Learning Health Care rests on a compact between patients and the health system. On one side of the compact, patients allow researchers and others working within the system to use their personal health information to generate new knowledge. On the other side of the compact, patients benefit from this knowledge because, when the system reliably and systematically adopts the innovations and improvements from the new knowledge identified, better care results.

In both scientific and ethics circles, however, considerably more attention has been paid to the data collection side of this compact than to the translation side; yet translation shortfalls, which occur frequently, are deeply problematic morally. First, translation shortfalls limit the good that can result from collecting and analyzing patient information. Second, they disrespect LHCS patients who helped the system generate new knowledge and to whom promises were made that care-related improvements would result from their contributions.

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We have outlined elsewhere a set of seven ethical obligations for Learning Health Care, including the obligation to respect the rights and dignity of patients.⁵ Respect for patients is a fundamental ethical commitment, generally requiring informed consent, confidentiality, and interactions infused with empathy, cultural sensitivity, and language that is understandable to patients and research participants. Importantly, however, research ethics has operationalized the duty to respect patients almost entirely through the requirement of informed consent, and too often ethics has equated respect for patients with respect for their autonomy. Informed consent is a cornerstone of ethical research. Yet, in limiting what respect requires only to questions of when and whether consent is needed, other important ways to demonstrate respect to patients whose health information will be used to advance learning get overlooked. If explicit consent for ongoing data collection and use is streamlined or waived, these additional respect-promoting practices become all the more important. We suggest that three specific respect-promoting actions are morally required in a LHCS: *engagement* with patients about ongoing learning activities, *transparency* with patients about ongoing learning activities, and *accountability* in implementing what is learned.

2 | ENGAGEMENT

The National Academy of Medicine's landmark report *Best Care at Lower Cost* advocated that patients be engaged in helping to inform which learning and improvement activities should be given priority.¹ The Patient-Centered Outcomes Research Institute (PCORI) requires that researchers build patient engagement into most of their funded research.⁶ In a LHCS, we similarly endorse engaging patients in setting priorities for the system's learning generation. However, in our view, the responsibility to engage patients in a LHCS goes deeper. LHCS should also seek patient input in determining how best to *inform* patients about ongoing learning activities and in determining which activities should require traditional informed consent and which may go forward with streamlined or broad consent approaches. Specifically, patients should be engaged in robust discussions about which learning and improvement activities should go forward as a routine part of health care operations (as currently happens with quality improvement), which should proceed with a meaningful opportunity for individual patients to “opt-out” of the activity, and which should proceed only with the affirmative, express permission of the patient. Doing so would require a LHCS to establish new mechanisms—whether through a patient board or any number of other engagement strategies—to both equip patients with sufficient background to participate in meaningful decisions about which types of data gathering activities should be associated with which types of patient disclosure or consent, and to ensure an environment in which patient input is taken seriously.

3 | TRANSPARENCY

If a LHCS is to be respectful of the patients whose health information they use, it is important for the system to be transparent about these uses. A LHCS can employ any number of media including TV monitors,

newsletters, or websites to inform patients about specific learning activities that are being planned or underway and also to reiterate to patients that data are collected expressly as part of the system's commitment to continuously improve care through ongoing learning. This commitment to ongoing learning is something a system should be proud of, and something it is likely most patients will value. The same communication strategies used for transparency can also be used by the system to demonstrate accountability to patients (discussed further below), in routinely sharing what changes in practice have resulted from ongoing learning activities.

A LHCS's obligation to be transparent about the uses of patient health information is not restricted to learning activities. Remarkably, despite the vast number of parties who view patients' records, debates about what, if anything, needs to be disclosed to patients and whether consent should be obtained occur almost exclusively when patient data is to be accessed for clinical research. As a matter of respect for its patients, a LHCS should be transparent about *all* third party uses of patients' data, including not only possible uses by researchers, but also about ongoing quality improvement activities, the routine sale of clinical and pharmaceutical patient health information to third parties, and the sharing of patient data with certain state registries.⁷

4 | ACCOUNTABILITY

The direct ethics connection between knowledge generation in learning health care and translation of learning into practice is, of course, similar in moral character to the relationship between the biomedical research enterprise and the public, and the relationship between biomedical researchers and their research participants. Societies invest in biomedical research with the expectation that innovations borne of that investment ultimately will be translated into improved health and quality of life. People volunteer for research with the understanding that their participation contributes to biomedical science and, in some cases, to improving how health care is delivered. The tension that results when the compact is compromised in a Learning Health Care System, where promises to patients are likely more personal and more intimate, is particularly problematic ethically. In a continuously learning system, a great deal of personal health information, by design, will be aggregated routinely in the service of ongoing improvement and innovation. The goal is for continuous data collection and analysis to translate into benefits for patients *within the same system* in the relatively short term. This is not the case in traditional biomedical research, even when the research is conducted in a clinical setting. Researchers do not promise research participants that they, personally, will be involved in changing clinical practice based on the findings of their research or even that such changes will necessarily occur in the near term or in that same setting. Rather, the representation in the standard research context is broader, vaguer, and more aspirational— that the goal is for research findings to influence future care. Although admittedly this state of affairs is problematic and deserves more attention, researchers are not generally considered to have any responsibility for ensuring the translation of research into practice beyond making their findings available to others through publication and other means.

By contrast, a Learning Health Care System is an entity that, by definition, is committed to both sides of the equation: to the ongoing collection, aggregation and analysis of patient information *and* to the routine translation of what is learned from this information into improved clinical practices within the same system. The promise that foregoing much control over one's data will yield improvement in care within the same system is a promise such a system *can* make; indeed, this commitment must be a proactive priority, with procedures and systems in place to ensure that care actually improves from aggregated patient data, and for which it absolutely must be accountable. A LHCS must have experts in place to determine in a given period of time when the evidence that is generated is sufficiently strong and clinically important to be translated into changes in practice and then to make sure that the changes actually occur.^{8,9} For example, Geisinger's ProvenHealth Navigator actively coordinates primary care teams, nurses trained in case management, preventive care planning, electronic health record review, data modeling, and real-time tracking of patient health in efforts to improve certain health outcomes¹⁰ and to reduce acute inpatient care.¹¹ Whether through care providers and patients influencing which questions are studied, or system leadership requiring care centers and researchers to demonstrate how care systematically changes, a *systems* approach will be needed to ensure that implementation is not merely the goal of learning, but a goal that is regularly realized.

The LHCS has the potential to generate transformative gains in the quality and efficiency of health care, and to hand in hand also increase the respectfulness and fairness with which care is delivered. Historic shortfalls in research translation and implementation are deeply troubling morally. In a Learning Health Care System, they are ethically unacceptable. Unless as much attention is devoted to the "care" part of LHCS as is being devoted to the "learning", the promise of the system, and the moral foundation on which it is based, will falter. The LHCS, in its conception, relies on a critical feedback loop between patients contributing data to the LHCS and the system, in turn, delivering to patients higher quality care based on what was learned. Fulfilling both parts of this compact, and identifying ways to incorporate additional respect-promoting elements into the system's design, will provide a firm ethical foundation to an approach that, from its outset, is committed to improving the well being of patients.

CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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