# Learning Health System — Moving from Ethical Frameworks to Practical Implementation

## Currents in Contemporary Bioethics

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### Introduction

In 2007, the National Academy of Sciences, Engineering and Medicine (NASEM; formerly the IOM) laid out its vision for a transformative system to improve health care quality while managing complexity, reducing inefficiency, and curbing cost. This "learning health system" (LHS) is an aspirational model that addresses diverse shortcomings in the current health system, including research processes that are inefficient and poorly targeted to the real-world needs of patients and clinicians and a failure of clinical systems to implement evidence once generated.[1] The LHS model aspires to address these gaps by capitalizing on new technological capabilities such as electronic medical records (EMRs) and data aggregation systems to collect data from everyday clinical encounters and to use those data to drive learning and care improvement.

While the LHS model promises to improve both research and clinical care, it also presents ethical challenges. Much of the relevant ethics literature has focused on informed consent and the acceptability of waiving or streamlining consent procedures for at least some types of learning activities. This debate over consent suggests a deeper challenge, namely, how can health systems fulfill the ethical commitment of respect for persons in the context of an LHS? Recently, Nancy Kass and Ruth Faden have argued that, by operationalizing the commitment to respect for persons almost exclusively via informed consent, research ethics has overlooked other important ways to demonstrate respect for persons. They propose additional respect-promoting practices to fulfill this obligation in the context of an LHS. In what follows, we describe these practices, explore how an LHS can implement them, and highlight areas for future research.

### Overview of Learning Health Systems

Perhaps the most influential description of an LHS comes from the 2007 NASEM report, which defines the LHS as a system in which "science and informatics, patient-clinician partnerships, incentives, and culture are aligned to promote and enable continuous and real-time improvement in both the effectiveness and efficiency of care."[2] The NASEM model of an LHS was presented as a broad-ranging model, and has been adapted and applied to a diverse range of contexts, from individual delivery systems to national networks.[3] However, five key components are central to the LHS approach: (1) a structural commitment to a **bidirectional feedback loop**, in which data collection is embedded into care delivery processes, and care is changed in response to evidence generated;[4] (2) a **partnership between research and**

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**clinical operations**, including the mutual commitment to use scientific knowledge and routine evaluation to rapidly and routinely drive improvement in care delivery;[5] (3) a **robust data infrastructure**, designed to enable information to be collected as a by-product of care delivery, to both reduce the inefficiencies associated with traditional research and ensure that evaluation is relevant to real-world contexts;[6] (4) **analytic capabilities to make use of existing clinical data** that identifies and evaluates the effects of routine heterogeneity in treatment approaches across the health system, and to facilitate experimental designs such as *point-of-care trials*; and (5) a **means by which to integrate new knowledge into the delivery of care**, such as through *adaptive guidelines* and *clinical decision-support systems*.[7] As aptly summarized by Amy Abernathy, an LHS is thus one in which the "care of an individual patient is informed by the care of patients before her or him, and his or her care is reinvested into a system of continuously aggregating data to support future discovery."[8]

In the United States (U.S.), numerous institutions have made a public commitment to the LHS model.[9] Non-profit integrated delivery systems like Geisinger Health System in Pennsylvania, Group Health Cooperative in Washington, Kaiser Permanente Colorado, and Intermountain Healthcare in Utah have implemented comprehensive structural reorganizations of their respective systems consistent with an LHS.[10] Government actors are undertaking similar efforts. For example, the Veteran's Health Administration (VA), the largest integrated health care system in the U.S., studies the ongoing care that patients receive through both observational studies and embedded "pragmatic" trials, designed to evaluate the effectiveness of interventions in real-life practice settings. Regardless of their particularities, these efforts aim to improve care more quickly and reduce the costs associated with traditional clinical trials.

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## Ethical Considerations

Strong moral justifications support adoption of the LHS model, as "systems that do not aim to study what they do and make improvements on the basis of what they learn inadvertently harm patients, maintain disparities, and waste resources."[11] The LHS model thus offers tremendous value to patients and society, improving both the quality and efficiency of care. The model also has the potential to advance health equity, as an LHS is well-positioned to more fairly distribute the benefits and burdens of knowledge generation, both because systematic learning from observational data can better include those populations historically underrepresented in research, including pregnant women, minorities, and children, and because the system reduces "free riding" in which individuals receive the benefit of knowledge without participating in its generation.[12] Nevertheless, major ethical challenges accompany transition to the new paradigm and ongoing implementation. A central issue is the poor fit between the LHS model and existing ethical and regulatory frameworks, which rest upon a sharp delineation between research and clinical care.[13]

### *Poor Fit of Traditional Ethical and Regulatory Frameworks*

As traditionally understood, the primary goal of clinical care is therapeutic — to preserve or advance the health of the individual patient.[14] In contrast, the primary commitment of clinical research is to science and the advancement of general medical knowledge, meaning protection of the rights and interests of individual patient-subjects necessitates comprehensive informed consent processes and extensive oversight.[15] In an LHS, however, this distinction is often difficult to sustain, as data systems, treatment recommendations, and strategies to improve care are integrated into the same systems that, simultaneously and by design, serve multiple purposes.[16] Indeed, many activities in an LHS are not easily classified as either care or research. For example, when large data systems are created for multiple purposes, the same activity may be designed both to treat a patient and to gather data. In such contexts, the continued reliance on the research-clinical care distinction becomes increasingly problematic, creating a regulatory environment plagued by "delays, confusions, and frustrations."[17]

### *Demonstrating Respect for Patients in an LHS Environment*

As Kass and Faden have argued, an LHS rests on a compact between patients and the health system. Patients allow the use of their personal health information to generate new knowledge, and patients in turn benefit from this knowledge because, when systems reliably and systematically adopt the innovations and improvements from the new knowledge identified, better care results.[18] As they note, considerable attention has focused on the data collection side of this compact, yet issues related to the translation side have often been overlooked. Failures to translate knowledge are both com-



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mon and morally problematic.[19] To remedy this neglect, Kass and Faden have proposed three respect-promoting practices as central to the ethical conduct of any LHS: **engagement** with patients about ongoing learning activities (including involvement in decisions about which type of learning activities are undertaken within a system), **transparency** with patients about ongoing learning activities (including that patient data is routinely collected as part of the system's commitment to continuously improve care, as well as about specific learning activities underway in the system), and **accountability** in implementing what is learned (requiring structured procedures and systems to ensure that care actually improves from aggregated patient data).[20] Below we examine each practice, suggest ways by which it might be implemented at the health system level, and identify open questions related to implementation.

### PATIENT ENGAGEMENT

Kass and Faden's call for patient engagement as a central pillar of the ethical operation of an LHS is consistent with a broader trend towards engagement of patients and participants in clinical care and in research. Several large funding agencies have now made rigorous engagement of patients and other stakeholders a necessary condition for research funding.[21] While there is no consensus definition of patient or participant engagement, there is broad agreement that *bi-directional* communication between clinicians/researchers and patients/participants is critical.[22] Further, engagement is believed to be valuable not only because it promotes respect, but also for its pragmatic benefits, such as improving the design and implementation of research.[23] An LHS arguably has a "deeper" obligation to engage patients than a traditional health system, involving them not only in decisions about what types of learning activities it should undertake, but also in determining how best to inform patients about those learning activities, and the form of consent or authorization that should be required.[24]

Engagement can take several forms, depending on the goals for involvement of patient-participants. For example, surveys can be used to measure general acceptance of and comfort with various governance or consent options or to assess willingness to participate under hypothetical conditions. Alternatively, focus groups or community engagement studios can be used to elicit the feedback of selected members of the patient population in a group setting.[25] Community advisory boards, or separate standing committees constituted by representatives of patients, research participants, or the broader community, may be used to advise LHS leadership or researchers on stakeholder engagement, review patient-oriented materials, and provide input on operations to evaluate and support acceptance in the broader community. Patients may also be included as representatives on steering committees or oversight boards, supporting such processes as reviewing proposed studies and determining the appropriate consent approach. Moving forward, an LHS should also consider novel means of engagement, such as app-based platforms to facilitate engagement of patients with both prospective and ongoing clinical trials and other learning activities.[26]

Ultimately, health systems will likely need to use a combination of engagement strategies tailored to the specific goals for involving patients in decision-making, suggesting several areas for future inquiry. For example, how should patient-participants be selected for engagement? In recent years, considerable scholarship has examined methods for patient engagement. Yet there has been less examination into "who" should be engaged.[27] As Emily Largent and colleagues have argued, this question deserves more systematic attention. As they note, "Patients are not a monolithic group…Accordingly, a choice to engage some patients instead of others will have important consequences for which perspectives inform research," affecting not only the instrumental value of engagement, but also the downstream ethical implications.[28] Similar observations have been made about the need to be more thoughtful in deciding whether the goals of a specific engagement activity would be best served through patient involvement or public involvement.[29] Further work is needed to better specify which selection approaches are best suited for different types of engagement activities.[30]

In addition, questions remain as to how health systems can best incorporate patient views into decision-making about oversight of learning activities. For example, several recent empirical studies have found that many patient-participants and other stakeholders believe that streamlined consent approaches for low-risk comparative effectiveness research (CER) are acceptable.[31] However, questions persist regarding whether and how health systems will incorporate these preferences into decisions regarding research ethics oversight practices, and what other influences are prominent.

### TRANSPARENCY

Transparency is a key component required for the success of an LHS. As described by Kass and Faden, for an LHS to be respectful of the patients whose health information they use to improve knowledge and care, it must be transparent about the uses of that information. More pragmatically, overlooking the importance of early and clear community education could lead to future issues if clinical data are used for purposes that patients are unaware of or disagree with.[32]

As with engagement, there is generally widespread endorsement for the value of transparency. Yet further work is needed to specify the content of this obligation. First, by what mechanism(s) should transparency occur? Several mechanisms by which an LHS can inform patients about planned or ongoing learning activities have been proposed. For example, an LHS might provide informational literature to all current and prospective patients regarding the system's commitment to research-care integration.[33] To notify patients about specific learning activities, an LHS



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could use newsletters, websites, flyers or TV monitors within patient waiting rooms, and notices within patient portals in EMRs.[34] To date, empirical data is lacking regarding issues such as the relative effectiveness and reach of different modalities, as well as patient preferences for the form(s) by which information should be shared. Future research is needed to understand the best ways to make patients aware of specific learning activities, as well as the broader intent for data collection as a means to facilitate continuous improvement.

Questions also remain about the extent of the obligation for transparency regarding the use of patient health information. For example, while historical debates regarding disclosure to patients about uses of their health data have largely focused upon access for clinical research, patient data is regularly accessed by third parties without express patient permission, including for such diverse uses as ongoing quality improvement, billing, registries, and the routine sale to third parties of deidentified data for pharmaceutical marketing or other purposes. Kass and Faden argue that patients should similarly be made aware of these uses of their health information.[35] How such disclosure should occur and the resultant impacts remain unexplored.

**Accountability**

By its very definition, an LHS is committed not only to collecting data to generate evidence, but also to routinely using that evidence to drive improvement in the delivery of clinical care. Historically, health systems have done a poor job of integrating knowledge to drive care improvement. According to one commonly cited metric, it takes 17 years between when a new element of clinical knowledge is generated and when that knowledge is incorporated into routine clinical practice.[36] While this lag is generally morally troubling, it is ethically unacceptable in the context of an LHS, given the explicit commitment of the LHS model to direct application of evidence to improve care within the health system from which that evidence was derived.[37]

Fulfilling a commitment to accountability will require the development of mechanisms by which to ensure that patients within an LHS benefit from the use of their data and samples.[38] In the LHS literature, accountability is described as requiring such things as creating and embedding evidence-based clinical practice guidelines into clinical workflows to shape the routine delivery of care.[39] Additional features might include permitting patient access to raw data and offering the return of individual study results,[40] as well as a system-level commitment to develop, plan, prioritize, and implement quality improvement projects, and a corresponding mechanism to disseminate and implement changes supported by the results of those projects. Future work is needed to explore such issues as how best to incorporate knowledge gains into clinical delivery systems to drive care improvements, as well as how patients should be informed about the ways in which their data contributed to these advances.

**Conclusion**

Supporters of the LHS model point to its promise to dramatically improve both research and clinical care. While strong moral justifications support adoption of the LHS model, transformation also presents several ethical challenges. We have described three practices — engagement, transparency, and accountability — proposed as means to demonstrate respect for persons in the context of this changing landscape. We have also outlined means by which these practices might be implemented and identified open questions associated with implementation. In keeping with the commitment to continuous learning that informs the LHS model, we embrace work exploring additional practices that would support health systems in demonstrating respect for persons as they generate and apply knowledge to advance health.

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