## The Science of Learning Health Systems: Foundations for a New Journal

Charles P. Friedman, PhD, Department of Learning Health Sciences, Medical School, University of Michigan, Ann Arbor, MI cpfried@umich.edu

Nancy J. Allee, MLS, MPH, Taubman Health Sciences Library, University Library and Department of Learning Health Sciences, Medical School, University of Michigan, Ann Arbor, MI

Brendan C. Delaney, MD, Medical Informatics and Decision Making, Imperial College, London, UK

Allen J. Flynn, PharmD, CPHIMS, Department of Learning Health Sciences, Medical School, University of Michigan, Ann Arbor, MI

Jonathan C. Silverstein, MD, MS, FACS, FACMI, Medical Informatics, Tempus and Kanter Health Foundation, Chicago, IL

لسب

Kevin Sullivan, PhD, Department of Computer Science, School of Engineering and Applied Science, University of Virginia, Charlottesville, VA

Kathleen A. Young, MA, Department of Learning Health Sciences, Medical School, University of Michigan, Ann Arbor, MI

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1002.10020

This article is protected by copyright. All rights reserved.

#### The Imperatives

In recent years, health systems across the United States and around the world have faced persistent challenges including the underutilization of necessary care, the overutilization of inappropriate care, rising costs, disparities in access to care, patient safety concerns, outdated public health infrastructures, and an oft-cited 17-year latency between bench and bedside.<sup>1, 2</sup> This well-documented state of the health of individuals and populations generates an imperative to improve human health, worldwide, through system-level innovations to address what are increasingly recognized as system-level problems.

A proliferation of knowledge about "what works" in health care, availability of ever more powerful and affordable information technology, increasingly routine digital documentation of health care delivery, accumulating understanding of how to inculcate behavior that promotes health, among other factors, combine to place these system-level innovations within reach. A second imperative thus challenges us to capitalize on these opportunities.

System-level improvement requires a broad and diverse intellectual community. The necessary trans-disciplinary community will be comprised of scholars with expertise in social, political, technical, and clinical fields, along with many others who bring critical experience from practice. It follows that a third imperative is to form this community and provide it with a gathering place for its evolving scientific ideas and insights.

#### Learning Health Systems (LHS)

A vision for Learning Health Systems (LHS) has emerged in response to these imperatives. Since it was initially conceived by the National Academy of Medicine (formerly, the Institute of Medicine) in 2007,<sup>3</sup> the LHS has evolved from an intriguing idea to a nascent reality.

The concept of the Learning Health System is perhaps best understood by examining each of its component words. *Learning* refers to the capability for continuous improvement through the collection and analysis of data, creating new knowledge, and the application of the new knowledge to influence practice. *Health* is both an end-goal of universally recognized benefit to humanity, and a domain of human endeavor seeking to achieve that end. A *system* consists of component parts acting in unison to achieve goals not attainable by any subset of the components. Integrating these terms, health systems become *learning* health systems when it they acquire the ability to continuously, routinely, and efficiently study and improve themselves.

This definition suggests five observable features of Learning Health Systems:

- Every patient's characteristics and experiences are securely available as data to *learn* from;
- Best practice knowledge derived from these data is immediately available to support health-related decisions by individual members of society, care providers, as well as managers and planners of health services;
- Improvement is continuous through ongoing study addressing multiple health improvement and related goals;
- A socio-technical infrastructure enables this to happen routinely, with a significant level of automation, and with economy of scale;
- Stakeholders within the system view the above activities as part of their culture.

Learning Health Systems can exist at any level of scale: a single organization, organizations within an identified geographic or jurisdictional region, a network of organizations, an entire nation, groups of nations, or the entire world. To the extent that the infrastructures supporting continuous learning are compatible across distinct systems, there is potential to form systems at higher levels of scale through composition of systems at lower levels.

#### A National and International Movement

Learning Health Systems, at varying levels of scale, are appearing across the United States, framed by federal policy affirming the LHS as the pinnacle goal for the next decade.<sup>4</sup> At the organizational level, institutions such as Intermountain Health Care,<sup>5</sup> Kaiser Permanente, <sup>6</sup> and as described in this Journal, <sup>7</sup> Johns Hopkins University have established the LHS as a goal and have made significant progress toward achieving the characteristics described above. Networks of institutions seeking to achieve significant aspects of LHS capability abound in the U.S., including networks funded through PCORI<sup>®</sup> focused on comparative effectiveness research across disease types, disease focused initiatives such as CancerLinQ, <sup>9</sup> and statewide efforts such as the Michigan Surgical Quality Collaborative.<sup>10</sup> National programs aligned with the LHS include the Precision Medicine Initiative of the National Institutes of Health, <sup>11</sup> and EvGen from the Food and Drug Administration.<sup>12</sup> These efforts are broadly supported by a series of 11 reports from the U.S. Institute of Medicine dating to 2007, <sup>13</sup> and by endorsement of a consensus set of LHS *Core Values* by 105 organizations spanning the health spectrum.<sup>14</sup>

Similar trends are in evidence around the world. The TRANSFoRm project, funded by the European Commission, addressed fundamental problems in developing infrastructure to support continuous learning.<sup>15</sup> TRANSFoRm gave rise to the first "LHS in Europe" meeting in 2015. The European Institute for Innovation through Health Data, described in this

journal, <sup>16</sup> reflects the growing LHS movement across the continent. In the United Kingdom, the work of the Farr Institute <sup>17</sup> closely aligns with the LHS. In Asia, a collaboration between the nation of Taiwan and the Tohoku region of Japan is growing infrastructure for an LHS.<sup>18</sup>

## A Science of Learning Systems

Perhaps of greatest importance is a widely shared vision that achievement of an LHS is an asymptotic goal that will never be fully achieved. The LHS will be shaped and reshaped by new health problems, evolving policies, innovation in health delivery and behavior, with much of this innovation stimulated by the LHS itself. Moreover, realizing an LHS requires attention to an unprecedented range of deep scientific problems that may require entire new methods and modes of thinking, approaching the status of a new science.

It is possible, but not accurate, to view the achievement of a Learning Health System at any level of scale, as an exercise in construction from a blueprint. This conceptualization belongs to an earlier era. It fails to recognize that the LHS is a new and fundamentally different type of system: a *cyber-social* system, where: "The system as a whole—not just the digital infrastructure, but also networks of people and institutions—will have to be understood not just as users of a technological infrastructure, but also as parts of the information system itself."<sup>19</sup> Moreover, it fails to recognize that, as the scale of the LHS increases, its characteristics approach those of an ultra-large scale system <sup>20</sup> that exhibits unique characteristics, behaves in ways fundamentally different from systems at smaller scale--and requires new approaches to system conception, design, implementation, orchestration, evolution, certification, and governance.

Workshops sponsored by the U.S. National Science Foundation held in 2013, 2015, and 2016<sup>21</sup> have lent credence and shape to both the cyber-social and ultra-large scale

systemic character of the LHS, and have identified many fundamental research questions prerequisite to achieving learning health systems at any level of scale, and more specifically to achieving highly functional LHSs that meet to significant extents four key requirements identified at the 2013 workshop<sup>21</sup>:

- A system that is trusted and valued by all stakeholders;
- An economically sustainable and governable system;
  - An adaptable, self-improving, stable, certifiable, and responsive system;
  - A system capable of engendering virtuous cycles of improvement.

These four requirements suggest the range of disciplines—spanning the behavioral, social, information, computing, and mathematical sciences as well as engineering--required to carry out the needed research and development. Transcendent research challenges—for example, achieving a scalable infrastructure to support continuous learning—may require new methods and new modes of thinking that evolve naturally from the admixture of these disciplines.

### <u>The Journal</u>

This vision of a different science, and perhaps even a new science, is the foundation for this new Journal. This journal seeks to be a virtual space for gathering the diverse community increasingly focused on this science. We, the editors, welcome articles that report research relating to cyber-social systems as applied to health. The scope of this science is very broad, but its domain can be generally described in relation to the four key functional characteristics of an LHS, as listed just above. The range of methods applicable to investigations within this Journal's scope is similarly wide, drawing from a complete spectrum of basic disciplines. It follows that achieving an LHS of ultra-large scale will require new forms of collaboration at ultra-large scale.

The editors welcome articles of several different types, exemplified by this first issue of the Journal<sup>22</sup>:

*Commentaries* express views or expert opinions of community members on topics of pertinence and importance. This issue features a commentary by Dipak Kalra and colleagues on the new European Institute.<sup>16</sup>

*Research Reports* describe original data-driven investigations to design or model, formulate or develop, enable or facilitate, implement, assess or evaluate learning health systems. This issue includes two research reports: an article by Richard Tannen <sup>23</sup> and colleagues introducing statistical methods for drawing potentially causal conclusions from observational data; and an article by Stephanie Morain and colleagues that draws insights from interview data on how health systems transition to learning systems.<sup>24</sup>

*Technical Reports* are similar to research reports, but describe models or architectures underlying any aspect of a Learning Health System. This issue features a report by Christel Daniel and colleagues addressing the technical methods required to achieve cross-border interoperability.<sup>25</sup>

*Experience Reports* describe the development of functioning learning systems within health settings at any level of scale, and experiences in working across levels of scale. This issue includes an experience report from Peter Pronovost and colleagues reporting on the journey of Johns Hopkins medical center toward becoming an LHS.<sup>7</sup>

Consistent with the global interest in the LHS is a distinct international character to this Journal. We are proud to have 10 nations represented on our Editorial Board and that the authors of the articles in this first issue represent 6 different nations.

لسب

We hope that this Journal will itself become part of the cyber-social infrastructure of the LHS. We invite all who share the vision of the Learning Health System to use this Journal to share their insightful viewpoints, new knowledge, and important experiences.

ပ လ Author Manu

## DRAFT Unformatted references

# Friedman article references:

# The Science of the Learning Health System: Foundations for a New Journal

- 1. Balas E., Boren S.A. Managing clinical knowledge for health care improvement. In: Yearbook of Medical Informatics; 2000:65-70.
- 2. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: Understanding time lags in translational research. *J R Soc Med.* 2011;104(12):510-520. doi:10.1258/jrsm.2011.110180.
- 3. The Institute of Medicine. Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care.; 2011.
- 4. Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0.; 2014. http://www.healthit.gov/sites/default/files/nationwide-interoperabilityroadmap-draft- version-1.0.pdf.
- 5. Ovretveit J, Nelson E, James B. Building a learning health system using clinical registers: A non-technical introduction. *Journal of Health Organization and Management*. 2016;30(7):1105.
- 6. Klein, S, Hostetter, M. In Focus: Learning Health Care Systems <u>http://www.commonwealthfund.org/publications/newsletters/quality-</u> <u>matters/2013/august-september/in-focus-learning-health-care-systems</u>
- Pronovost P, Mathews S, Chute C, Rosen A. Creating a Purpose Driven Learning and Improving Health System: The Johns Hopkins Medicine Quality and Safety Experience. Journal of Learning Health Systems. 2017;1(1):x-x.
- 8. Clinical Data and Patient-Powered Research Networks Awarded Projects. 2015. http://www.pcori.org/research-results/pcornet-national-patient-centered-clinical-research- network/clinical-data-and-0.
- 9. CancerLinQ LLC, a subsidiary of the American Society of Clinical Oncology, <u>www.cancerlinq.org</u>. Accessed: November 5, 2016.
- 10. Michigan Surgical Quality Collaborative, <u>http://www.msqc.org</u>.

Accessed: November 5, 2016.

- 11. Precision Medicine Initiative of the National Institutes of Health, <u>https://www.nih.gov/precision-medicine-initiative-cohort-program</u>. Accessed: November 5, 2016.
- Califf RM, "Evidence Generation: Moving into the Modern Era", U.S. Food and Drug Administration, <u>http://nationalacademies.org/hmd/~/media/Files/Activity</u> <u>%20Files/Research/DrugForum/2016-OCT-19/Califf\_Presentation.pdf</u>. Accessed: November 5, 2016.
- 13. "The Learning Health System Series", National Academies Press, 2007-2011, <u>https://www.nap.edu/catalog/13301/the-learning-health-system-series</u>. Accessed: November 5, 2016.
- 14. Learning Health Community, "Endorsers of the Core Values Underlying a National-Scale Person-Centered Continuous Learning Health System", <u>http://www.learninghealth.org/endorsers/</u>. Accessed: November 5, 2016.
- 15. Brendan C. Delaney, Vasa Curcin, Anna Andreasson, et al. Translational medicine and patient safety in europe: TRANSFoRmarchitecture for the learning health system in europe. *BioMed Research International.* 2015:1. http://dx.doi.org/10.1155/2015/961526
- 16. Kalra D, Stroetmann V, Sundgren M et al. The European Institute for Innovation through health data. *Journal of Learning Health Systems.* 2017;1(1):x-x. doi:10.1002/Irh2.10008
- 17. Farr Institute <u>http://www.farrinstitute.org</u>
- 18. Tohuku Medical Megabank Organization. http://www.megabank.tohoku.ac.jp/english/timeline/20160527\_01/
- 19. Friedman C, Rubin J, Brown J, et al. Toward a science of learning systems: A research agenda for the high-functioning learning health system. *Journal of the American Medical Informatics Association: JAMIA*. 2014;22(1):43-50.
- 20. Northrop L. Presentation: "Ultra-Large-Scale Systems: Scale Changes Everything". Software Engineering Institute. Carnegie Mellon University. SMART Event. 6 March 2008.

http://resources.sei.cmu.edu/library/asset-view.cfm?assetID=21506

- 21. Cyber-Social Learning Systems (CSLS) Workshops: <u>http://cra.org/ccc/visioning/visioning-activities/2016-activities/cyber-social-learning-systems/</u>
- 22. The Journal of Learning Health Systems. Learning Health Systems, Wiley Online Library. <u>http://www.lhsjournal.com</u>
- 23. Tannen R, Yu M. A New Method to Address Unmeasured Confounding of Mortality in Observational Studies. *Journal of Learning Health Systems*. 2017;1(1):x-x. doi:
- 24. Morain S, Kass NE, Grossmann C. What allows a health care system to become a learning health care system: Results from interviews with health system leaders. *Journal of Learning Health Systems*. 2017:1(1);x-x. doi:10.1002/lrh2.10015
- 25. Daniel C, Ouagne D, Sadou E et al. Cross border semantic interoperability for Learning Health Systems: the EHR4CR semantic resources and services. *Journal of Learning Health Systems*. 2017;1(1):x-x. doi:10.1002/lrh2.10014

Author Ma