

The Learning Health System Series

Accelerating Progress Toward **Continuous Learning**

A National Academy of Medicine Meeting Summary



NATIONAL ACADEMY OF MEDICINE

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ACCELERATING PROGRESS TOWARD CONTINUOUS LEARNING

A National Academy of Medicine Meeting

June 29, 2017

Summary

Introduction

A learning health care system (LHS) is “one in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the care process, patients and families active participants in all elements, and new knowledge captured as an integral by-product of the care experience” (IOM, 2013). The goal of embedding continuous improvement and innovation into ongoing care is to reduce unjustified variation and improve carefully considered variation in care delivery, ultimately improving health care outcomes, reducing waste and improving efficiency, and reducing growth in health care spending.

Defining characteristics of a LHS include the availability of science and informatics that support real-time access to knowledge and digital capture of the care experience; patient-clinician relationships that support engaged, empowered patients and that value continuous improvement; incentives that are aligned for value and that support full transparency of information for care improvement; and a leadership-instilled culture of learning, with supportive system competencies (IOM, 2013).

The past 10 years have been a transformative time for health care. There has been a substantial increase in the use of health information technology, including the use of electronic health records, mobile devices, and applications, and the development of large, multisystem research networks. There have also been shifts in our understanding of how health should be managed, including the importance of social and behavioral services in improving health outcomes, and there have been steps taken to re-align incentives away from fee-for-service and toward paying for value.

To reevaluate where the United States is in terms of progressing toward a LHS and to consider key actions for the National Academy of Medicine (NAM) and the Agency for Healthcare Research and Quality (AHRQ) to accelerate future progress toward achieving continuous learning, the NAM, in partnership with AHRQ, hosted a day-long meeting on June 29, 2017 at the National Academy of Sciences Building. Meeting attendees included key thought leaders from federal agencies, large health care systems, professional societies, health information technology companies, public and private payers, and foundations and not-for-profit organizations (Appendix A). Each participant was also asked to submit written responses to two open-ended questions:

- What are the top three priorities for accelerating progress toward a continuously learning health system?
- What are the ways in which your organization might help lead the charge in advancing a continuously learning health system?

During the meeting, and following opening remarks from Michael McGinnis from the NAM and Gopal Khanna and Sharon Arnold from the AHRQ, sessions focused on several areas, including the key elements and characteristics of a LHS, how to move from theory to practice, priorities for LHS knowledge generation, and, finally, defining a LHS agenda (Appendix B). Each session began with introductory comments from a set of expert panelists followed by a moderated discussion among participants. This document describes the themes from the discussion and the written responses, summarizes ongoing initiatives designed to promote continuous learning mentioned by participants, and provides a list of key actions for accelerating progress toward continuous learning.

Barriers and Opportunities for Accelerating Progress Toward a LHS

Over the course of the discussion and in the written responses received, participants highlighted a number of barriers inhibiting progress toward a LHS as well as opportunities for addressing those barriers. The barriers and opportunities can be categorized in four areas: demand for continuous learning among health systems leaders and patients; clinician competencies for engaging in learning activities; data quality, access, and interoperability; and regulatory environments for research and quality improvement.

Demand for Continuous Learning among Health Systems Leaders and Patients

Several meeting participants commented on the need to sustain an enduring culture that supports continuous learning in health care practice. A necessary step to accomplishing this is fostering demand among health systems leaders and patients for transformational change. There are, however, several notable barriers to accomplishing this. One important issue is that health system leaders do not necessarily feel pressure to support efforts aimed at embedding continuous improvement and innovation in clinical care. The notion was advanced that it takes a “burning platform” to motivate change, and that, even though the health care delivery system is undergoing rapid change, and on the verge of substantially more as financing and organizational incentives change, the anticipated returns on investing in learning and improvement have not been adequately quantified.

To create demand among health system leaders, several participants recommended developing a business case for becoming a LHS that describes potential return on investment so that it becomes a bigger risk for systems not to change. To do this, systems should begin by implementing small pilot projects of only a handful of cases. Based on what is learned from those small pilots, systems should then make rapid changes, and should continue this process until the intervention is effective, while explaining to systems leaders the potential impact once a successful intervention is scaled. According to one participant, a significant threat to a LHS is premature scaling of ineffective interventions. Ultimately, as another participant noted, the goal should be to have health systems, providers, hospitals, and payers funding applied research and development as part of their operating budgets because federal funding will not be sufficient by itself to support continuous learning.

It is also necessary to create demand for cross-systems learning and data sharing. To foster data sharing and collaboration among systems, and potentially also between health systems and registries, one participant stated that it is important to first consider how a LHS should deal with, manage, and incorporate proprietary knowledge such as electronic health records (EHRs), research findings, and patented or trademarked delivery systems. Another participant recommended creating a matrix of systems and leadership with the goal of developing a better understanding of what different health systems are working on and how to coordinate efforts.

Also important is understanding the appropriate balance between health system independence and interdependence, because, as one participant noted, the LHS must operate at two levels: the microsystem level to address local issues and the macrosystem level to address issues across the U.S. health care system. There are numerous evidence gaps and research questions related to understanding effective approaches to preventing, diagnosing, treating, and monitoring health conditions that are relevant to improving care and outcomes at a national level. To address these questions, systems must work together to implement national, and sometimes international, studies. However, there are also systems-level issues, such as high readmission rates within certain systems, which require an understanding of the local context and the evaluation of interventions for systems-level improvement. These two levels interact in various ways and both are necessary for supporting continuous learning.

Demand for LHSs also needs to come from patients. Meeting participants noted that ongoing efforts to engage patients and caregivers in health care, health policy, and research have the potential to cultivate this demand among consumers. Future efforts should focus on identifying the most effective approaches for engaging patients and promoting the spread and scale of those approaches across the health care system.

Clinician Competencies for Engaging in Learning Activities

Meeting participants stated that currently, clinicians are often not expected to participate in system quality improvement and learning activities and do not necessarily have the time or the skills necessary to do so. A related issue is the high rate of clinician burnout and lack of resiliency. However, one participant commented that since clinicians are already dedicated to their patients, it is possible to change this expectation by defining a path forward and describing how a continuous improvement path would facilitate improvements in patient outcomes. Another opportunity is to align knowledge generation with activities that clinicians are already expected to do, such as continuing medical education or board certification. Additionally, to provide guidance to health systems on developing the skills required to support continuous learning, one participant recommended mapping out the expertise needed as well as the costs associated with developing that expertise. This exercise could also be useful to federal agencies, including AHRQ, and professional organizations as they consider how to support health systems in their efforts to transform into LHSs.

Other suggestions included developing training programs or research fellowships that provide clinicians with the skills necessary to be conversant in data competencies and to be active participants in learning; providing peer-to-peer clinician data to encourage clinicians to continue to improve; and embedding researchers in practice so they can act as consultants with patients and clinicians driving the care and the questions. Meeting participants also acknowledged ongoing payment reform efforts that incentivize the provision of high-value, instead of high-volume, health care in the U.S., noting that the scale and spread of value-based payment models requires continuous learning in order to be successful and is a necessary step to reducing clinician productivity pressure thereby allowing clinicians to be active participants in learning efforts.

Data Quality, Access, and Interoperability

As stated by one participant, there is a need to address the dysfunctional state of data liquidity and interoperability in the U.S. health care system. A necessary component to facilitating the networking required for a LHS is interoperable data systems (IOM, 2007). While work is ongoing in this area, additional efforts should focus on increasing standardization of data, both across and within systems.

A second issue is that data systems have been developed substantially to improve clinical billing efficiency and are therefore not optimized for supporting team-based care. Several participants commented that current systems are unable to provide information back to clinical care in a way that is valued by clinicians and that allows clinicians to question the data source. Related, data quality is inadequate for supporting inference due to issues such as differences in classification systems, missing data, and the presence of unmeasured confounding variables.

To improve the ability of EHR interfaces to inform clinical decisions, one participant recommended that funding agencies support the curation of research findings as interoperable decision support tools. Another participant suggested that the next generation of EHRs be created primarily to provide clinician decision support and to solve clinical learning problems. Related, other participants stated that the next generation should also improve outcome tracking and tracking patients across episodes of care as well as capabilities for incorporating patient-generated data and data on social determinants.

To improve the utility of data for supporting clinical care and learning, participants recommended that researchers develop novel methods for natural language processing and for using unstructured data. Learning can also be facilitated by open science, the creation of standardized data analytics, and prearranged logistics, such as relying on a centralized and consistent analytics team, leveraging standardized consent forms, working with the same institutional review boards (IRBs), and arranging base contracts with coordinating centers. Finally, learning can and is being facilitated by the creation of common data models, such as the ones being used by Sentinel and the National Patient-Centered Clinical Research Network (PCORnet), which allow network partners to map their data in the same consistent format (PCORnet, 2017; Sentinel, 2017).

Regulatory Environments for Research and Quality Improvement

According to several meeting participants, the regulatory oversight requirements for research and data sharing in the U.S. create disincentives to implementing the rigorous learning required for supporting continuous improvement. To highlight this issue, one participant described an effort within his health care system to improve colorectal cancer screening. To understand if sending a "colorectal cancer screening gift box" to individuals' houses once they reach a certain age increased screening rates, there was a discussion about sending out the packages in a randomized fashion versus sending the packages to everyone. The first option would facilitate learning but would also require IRB oversight and, potentially, informed consent, whereas the second option would not facilitate learning but would also not require any oversight.

A few participants suggested that it may be useful for researchers, clinicians, and others to work with their IRBs to develop solutions that are consistent with, and that leverage the flexibility that exists within, the Common Rule and other applicable regulations. These conversations should also take place at the national level to facilitate consistency across IRBs.

In addition to human subject research requirements, the Health Insurance Portability and Accountability Act (HIPAA) also creates barriers to sharing and using data. Participants noted

both the need for further discussions about data ownership and what that means in terms of revisions to HIPAA as well as the tendency of some health care organizations to interpret restrictions on health care information and data sharing in health care as substantially greater than they actually are. Another suggestion was to create data safe harbors to facilitate learning while protecting individual privacy.

Ongoing Initiatives to Support Continuous Learning

Despite the various barriers discussed, there was a shared belief among meeting participants in the feasibility and prospect of accelerating progress toward continuous learning and various stakeholders are pursuing activities to facilitate this advancement. For instance, different health systems have implemented training opportunities, systems and health information technology reform efforts, and programs that link medical and community services. Examples include the integration of internal quality improvement training at Baylor Scott & White Health for all levels of staff that supports LHS principles; the development of a Precision Medicine Analytics Platform by Johns Hopkins Medicine, in collaboration with the Johns Hopkins Applied Physics Laboratory, that acquires, integrates, and creates safe spaces to analyze data to improve clinical decision support; the establishment of “county health improvement organizations” at the University of Oklahoma to make it easier for primary care, public health, mental health, and community-based organizations to collaborate; and efforts by the High Plains Research Network to improve the delivery of rural health care in Colorado by providing guidance on disease management navigation services, innovative treatment solutions, and the linkage of medical practices with community and public health organizations.

Additionally, software companies, like IBM Watson, are investing in developing improved health information technology systems. Private payers, like Aetna, are advancing value-based contracting and value-based payment models. Professional organizations and several not-for-profit groups, like the Coalition to Transform Advanced Care, are developing guidance on best practices, tools, measures, and suggested payment models and disseminating that information to their members. Examples include the American Board of Family Medicine launching its PRIME Registry to facilitate quality improvement and learning across primary care physicians; the American Medical Association (AMA) partnering with the American Heart Association to implement its Target:BP initiative, which provides clinicians with evidence, tools, and other resources to reduce rates of high blood pressure among the patients they care for; the American College of Surgeons (ACS) launching a digital health information initiative; and both the AMA and the ACS developing secure and interoperable data platforms (ABFM, 2017; AHA and AMA, 2016). The ACS, in collaboration with the Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality and with funding and guidance from AHRQ, also recently launched the AHRQ Safety Program for Improving Surgical Care and Recovery, which aims to support hospitals in the implementation of evidence-based enhanced surgical recovery models (ARHQ, 2017a.).

At the federal level, several organizations are taking notable steps. For example, ClinicalTrials.gov is helping to foster a culture of open science by enabling full protocols, statistical analysis plans, and informed consent documents to be uploaded to the site as of July 2017. The U.S. Food and Drug Administration is developing guidance around the appropriate use of real-world evidence for supplemental new drug applications and biologics license applications. It also launched the Sentinel initiative in 2008 and the Innovation in Medical Evidence Development and Surveillance System in 2017 (Reagan-Udall Foundation, 2017; Sentinel, 2017).

The National Institutes of Health (NIH) has funded a variety of research networks and pragmatic clinical trials and established the NIH Collaboratory to support collaborative research among health systems (NIH, 2017). The Patient-Centered Outcomes Research Institute has also funded pragmatic clinical trials as well as PCORnet, a national “network of networks” to support continuous learning (PCORnet, 2017). AHRQ supports a number of activities that focus on helping health care delivery organizations build the capacity to move knowledge into practice in ways that enhance patient and clinician decision making. Ongoing activities, in addition to the safety initiative described above, include AHRQ’s clinical decision support initiative, which promotes the translation of evidence into practice through the development and implementation of decision support tools, and AHRQ’s Comparative Health Systems Performance Initiative, which examines how health systems promote the use of evidence-based practices in health care delivery in order to identify best practices (AHRQ b., 2017). AHRQ is also developing and supporting training opportunities for researchers to prepare them to participate in continuous learning activities.

To understand the impact these initiatives are having in transforming health systems in the U.S. into LHSs, it would be useful to identify the key elements of LHSs as well as benchmarks for measuring those key elements. Establishing benchmarks will help ensure that all stakeholders are working toward common goals and can be used to demonstrate how different initiatives, including those discussed above, are contributing to those goals.

Actions for Accelerating Progress Toward Continuous Learning

While these ongoing activities promote progress toward continuous learning, additional work is needed to completely address the barriers described by meeting participants. Based on the discussion that occurred at the June meeting, the most significant opportunities for action include the following:

Identifying key elements of learning health care systems that are tangible and measurable: Measuring progress in transforming health systems in the U.S. into LHSs requires the identification of and stakeholder agreement on benchmarks related to science, informatics, incentives, and culture that signal progress toward continuous learning. Once measurable elements are identified, standardized definitions for each of the measures should be created to facilitate consistency across systems and to allow systems to see how they are performing in comparison to one another. (Particularly relevant organizational stakeholders include the NAM, AHRQ, NIH, the Centers for Medicare & Medicaid Services (CMS), the Department of Defense (DoD), the Department of Veterans Affairs (VA), and professional societies.)

Improving data interoperability, liquidity, sharing, and ownership: A key feature of a LHS is leveraging data to embed knowledge generation and use into the care process. To enable the seamless use of data to support learning, health care software companies should develop information technology platforms that support interoperable data systems and the integration of patient-generated data and data on social determinants of health. Additionally, national organizations should convene stakeholders to develop approaches for addressing issues related to data ownership, governance, and sharing as well as to develop a shared understanding of how a LHS should manage proprietary knowledge from EHRs, research findings, and trademarked delivery systems. Finally, funding agencies should support the development of novel methodologies for using unstructured data as well as efforts to standardize data both across and within health systems. (Particularly relevant organizational stakeholders include the NAM, AHRQ, PCORI, software companies, health product manufacturers, payers, health care organizations, and professional societies.)

Leveraging technology to foster evidence translation and informed decision making: LHSs need to be capable of efficiently integrating evidence into clinical care. To facilitate this integration, it is important to support efforts that aim to understand how clinicians and patients like to receive information and develop functional interfaces and decision support tools for routinely displaying that information. (Particularly relevant organizational stakeholders include AHRQ, the Office of the National Coordinator for Health Information Technology (ONC), the Health Resources & Services Administration (HRSA), DoD, VA, the American Hospital Association, and professional societies.)

Creating a supportive regulatory environment: To address concerns that current human subject research regulations and privacy protections create disincentives to continuous learning, national organizations should convene representatives from health systems, IRBs, and the Office of Human Subjects Research Protections, as well as privacy experts, to discuss and develop appropriate approaches for oversight of learning activities, informed consent, and privacy protections that are consistent with existing regulations. Discussions should also consider areas where additional policy change is needed. (Particularly relevant organizational stakeholders include the NAM and professional societies.)

Engaging consumers in the learning process: Progress toward continuous learning requires support from patients and caregivers. Fostering support and trust requires active engagement of those individuals in conversations about institutional policy; data ownership, governance, and use; models of care, outcomes, and quality measures; and learning priorities and research. While there are mounting efforts to include patients and caregivers in various decisions, it is necessary to identify best practices for and measureable outcomes of patient and caregiver engagement. Once best practices are identified, those approaches should be disseminated and implemented across health systems. (Particularly relevant organizational stakeholders include AHRQ, PCORI, NIH, VA, and the research community.)

Providing clinicians with the skills and incentives to engage in continuous learning: Clinicians are well positioned to identify areas where learning activities could improve care. To enable clinicians to engage as active participants in continuous learning, AHRQ and others should continue to support the development of training opportunities and professional organizations should identify training programs that exist, such as the one at Baylor Scott & White Health and others developed or supported by AHRQ, and leverage those to create national standardized training models. Additionally, to create incentives to participate, professional societies and systems leaders could work to align participation in learning activities with other professional requirements, such as continuing medical education. Finally, funding agencies could release rapid-cycle funding mechanisms for clinician and researcher teams interested in continuous learning to support rapid innovation, evaluation, and design strategies for generating and adopting evidence into practice. (Particularly relevant organizational stakeholders include AHRQ, HRSA, CMS, the American Hospital Association, professional societies, and health systems leaders.)

Aligning payment incentives with high-value care: While both public and private payers are implementing value-based payment programs, a majority of care delivered to patients in the U.S. is still reimbursed on a fee-for-service basis. A focus on value requires continuous learning in order to be effective. As experience with value-based payment grows, payers should provide guidance on the types of evidence they need to support these programs as well as guidance on the approaches being used to define and measure value. (Particularly relevant organizational stakeholders include public and private payers, and care improvement and public health organizations.)

Building the business case for continuous learning: To build the business case and create demand for continuous learning, health systems should begin by implementing small pilot projects and making changes to promising interventions based on what is learned. Once effective interventions are identified, they should then be scaled. It is also important to highlight success stories or exemplars to health systems leaders as well as in the peer reviewed literature and at national conferences to show the impact that continuous learning can have in terms of improving care and bending the cost curve. (Particularly relevant stakeholders include employers, health services researchers, quality improvement professionals, clinicians, and health systems leaders.)

Changing the culture of care to one that values and supports continuous learning is challenging and will require ongoing support from a variety of different stakeholders. However, progress has been made and will continue as long as those stakeholders remain motivated and work together to address the remaining challenges related to building demand for learning, developing clinician competencies and incentives, improving data sharing and quality, and addressing regulatory barriers.

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Appendix B: Agenda



NATIONAL ACADEMY OF MEDICINE

Leadership Consortium for a Value & Science-Driven Health System

NAM-AHRQ LEARNING HEALTH SYSTEM MEETING

June 29, 2017 | National Academy of Sciences Building | Lecture Room
2101 Constitution Avenue NW | Washington, DC 20418

Meeting focus: Moving forward the vision of a continuously learning health system (LHS)

Core questions:

1. *Definition:* What constitutes a LHS? How might a LHS be defined, validated, and/or certified?
2. *Knowledge generation:* What is the state of LHS research? What are knowledge gaps/priorities?
3. *Implementation:* How might LHS be implemented and sustain in different systems and settings?
4. *Collaboration:* Which stakeholders should engage in the generation of new knowledge?
5. *Strategies:* What strategies exist for spreading the vision of continuous learning on a broad scale?

Expected outcome: Informing key action items for NAM, AHRQ, and the field to accelerate progress.

8:30 AM **Coffee and light breakfast available**

9:00 AM **Welcome, introduction, and meeting overview**

Welcome from the National Academy of Medicine

Michael McGinnis, National Academy of Medicine

Welcome from the Agency for Healthcare Research and Quality

Gopal Khanna, Agency for Healthcare Research and Quality

Sharon Arnold, Agency for Healthcare Research and Quality

9:30 AM **Key elements and characteristics of a LHS**

Participants will discuss strategies to define, measure, and/or certify learning systems.

James Madara, American Medical Association, moderator

Discussants:

David Martin, Food and Drug Administration

Jonathan Perlin, Hospital Corporation of America

Lewis Sandy, UnitedHealth Group

Andrew Gettinger, Office of the National Coordinator for Health IT

Q&A and Open Discussion

10:45 AM **Break**

11:00 AM **Moving from theory to practice**

Participants will discuss the strategies, costs, and essential stakeholders needed to implement and sustain continuous learning in different health systems and settings.

Peter J. Pronovost, Johns Hopkins Medicine, moderator

Discussants:

Brent James, Intermountain Healthcare

Andrew Masica, Baylor Scott & White Health

Q&A and Open Discussion

12:00 PM **Working lunch: Priorities for LHS Knowledge Generation**

Participants will explore the current state, gaps, and priorities of LHS research.

Mary Naylor, University of Pennsylvania School of Nursing, moderator

Discussants:

Jack Westfall, University of Colorado

Alan Weil, Health Affairs

Q&A and Open Discussion

1:00 PM **Defining the LHS agenda**

Participants will prioritize next steps for advancing continuous learning by 1) informing the development of a NAM Perspective; 2) exploring key action items for efforts by the NAM and AHRQ; and 3) discussing other potential collaborative endeavors.

Michael McGinnis, National Academy of Medicine, moderator

Discussants:

David Asch, University of Pennsylvania

Atul Gawande, Brigham and Women's Hospital, Harvard School of Public Health

Joe Selby, Patient-Centered Outcomes Research Institute

Q&A and Open Discussion

2:30 PM **Summary of next steps**

Comments and thanks from the Agency for Healthcare Research and Quality

Gopal Khanna, Agency for Healthcare Research and Quality

Comments and thanks from the National Academy of Medicine

Michael McGinnis, National Academy of Medicine

3:00 PM **Adjourn**

Members of the Leadership Consortium

Chair

Mark B. McClellan, MD, PhD
Director, Duke-Margolis Center
for Health Policy
Duke University

Members

David Blumenthal, MD, MPP
President
The Commonwealth Fund

Susan DeVore, MS
Chief Executive Officer
Premier, Inc.

Judith Faulkner, MS
Founder & CEO
Epic Systems

David T. Feinberg, MD, MBA
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Geisinger Health System

Joseph J. Fifer, FHFMA, CPA
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Healthcare Financial Mngmt Assn

Patricia A. Gabow, MD, MACP
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Atul Gawande, MD, MPH
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Paul Grundy, MD, MPH, FACOEM, FACPM
Global Dir. & CMO
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SVP & Chief Sci., Clin. & Reg Officer
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Peter Long, PhD
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Ex-Officio

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