The Learning Health Community

Vision

• The Learning Health Community ("Community") aims to mobilize and empower multiple and diverse stakeholders to collaboratively realize a national-scale (and ultimately global), person-centered, continuous and rapid learning health system (LHS).

• The vision for the LHS is embodied in the consensus LHS Core Values dated July 20, 2012; these LHS Core Values will guide and underpin the development of the LHS.

• Pursuant to the LHS Core Values, the LHS "will improve the health of individuals and populations. The LHS will accomplish this by generating information and knowledge from data captured and updated over time – as an ongoing and natural by-product of contributions by individuals, care delivery systems, public health programs, and clinical research – and sharing and disseminating what is learned in timely and actionable forms that directly enable individuals, clinicians, and public health entities to separately and collaboratively make informed health decisions... The proximal goal of the LHS is to efficiently and equitably serve the learning needs of all participants, as well as the overall public good."

• The LHS will leverage big data to effectuate knowledge generation and curation, tailored feedback, and ultimately transformative change in healthcare and health.

• The LHS will be dynamic; just as it facilitates a virtuous cycle of continuous improvement in healthcare and health, so too will the LHS engender its own continuous improvement and evolution driven by the creativity and innovation of the participants in the LHS. In much the way that the Internet will never be “done”, neither will the LHS.

• The national (and ultimately global) LHS will form by synergizing and harmonizing learning efforts currently underway as well as future emergent efforts of various scales and scopes.

Mission and Approach

• The Community’s mission is to galvanize a national grassroots movement in which multiple and diverse stakeholders work together to transform healthcare and health by collaboratively realizing the LHS vision. It will enable and catalyze positive steps toward achieving this vision.

• Members of the Community are bonded together by their shared determination to realize the LHS and their common belief in the LHS Core Values that serve to underpin it.

• The Community’s approach is grounded in a collective recognition that the LHS represents an ultra large scale cyber-social system. Its realization represents a profound socio-technical challenge as well as an extraordinary opportunity (and indeed, imperative) to effectuate profound and meaningful health system transformation. Achieving this vision is a challenge too great for any one organization, stakeholder group, or even sector; it can only be achieved through working together to give the gift of health to our children and our nation (and LHS Core Values such including “Inclusiveness” implicitly embrace this approach).

www.LearningHealth.org
Models of large-scale, sustained, multi-stakeholder collaboration that have enabled the development of public and private enduring and transformative innovations continuing to touch lives around the world and across generations will drive the Community’s operations.

By its grassroots nature, the Community is a self-organizing coalition of the willing whose work is driven by efforts of the participants that grow in the Community’s fertile environment conducive to the multi-stakeholder collaboration essential to realizing the LHS as a movement.

Organization

Though the mission-focused work of the community largely derives from the interests and initiatives of its members, guidance is provided by a twelve-member pro-bono Interim Steering Committee. The diversity of the expertise, interests, and stakeholder groups represented by the members of the Interim Steering Committee is intended to mirror that of the larger Community.

Via a Memorandum of Understanding, the Clinical Data Interchange Standards Consortium (CDISC) presently serves as the formal host of the Community, providing the Community with various hosting services (including, among other services, maintaining Community accounts and hosting the Community website) while enabling the Community’s full programmatic autonomy.

History

The Community grew out of the May, 2012 Learning Health System Summit sponsored by the Joseph H. Kanter Family Foundation. At the Summit, over 80 key stakeholders representing diverse organizations spanning healthcare worked to achieve consensus on the LHS Core Values that underpin and bond together the Community.

Many individuals responsible for planning the Summit on a pro bono basis continue to actively serve on the Community’s Interim Steering Committee.

To date, over 60 prominent national organizations, institutions, and companies have formally endorsed the LHS Core Values, publicly indicating their support for the collaborative realization of an LHS anchored in them.

Over 1,000 individuals are involved in various capacities in the grassroots movement.

The Community has had a strong and sustained presence at major regional and national conferences and events related to medical informatics and technology, health information management, public health, health administration, health law and policy, standards, and patient and caregiver advocacy.

Initiatives

Consistent with the emergent characteristics of the LHS itself and the grassroots approach of the Community, major steps toward realizing the LHS vision are accomplished through self-organizing, multi-stakeholder, collaborative initiatives.

Each initiative is hosted by a trusted neutral convener.

To date, the Community has catalyzed an initiative to identify Essential Standards to Enable Learning (ESTEL).

Other initiatives to begin soon include LHS governance and the creation of a technology “sandbox” for federated data sharing.

For ESTEL, participants have travelled across the country (and in a few cases, around the world) at their own expense to actively participate; others have engaged via webinars, conference calls, and email.

All initiatives will be designed to ensure that grassroots collaborative efforts result in sustained action and engagement as well as continued and meaningful impact.

www.LearningHealth.org
The Learning Health Community

**Interim Steering Committee Members**

- Holt Anderson, North Carolina Healthcare Information and Communications Alliance, Inc.
- Kate Berry, National eHealth Collaborative
- Jeffrey Brown, Harvard Pilgrim Health Care Institute
- Harry Cayton, Professional Standards Authority for Health and Social Care UK
- Charles Friedman, University of Michigan (*Interim Chair*)
- Claudia Grossmann, Institute of Medicine
- Robert Kolodner, ViTel Net and Open Health Tools
- Rebecca Kush, Clinical Data Interchange Standards Consortium (*Ex Officio*)
- Allen Lichter, American Society of Clinical Oncology
- Janet Marchibroda, Bipartisan Policy Center
- Frank Rockhold, GlaxoSmithKline
- Joshua Rubin, University of Michigan
- Jonathan Silverstein, NorthShore University HealthSystem
- Richard Tannen, University of Pennsylvania
- James Walker, Siemens Healthcare

[www.LearningHealth.org](http://www.LearningHealth.org)
68 Endorsements of the LHS Core Values*
(As of 12/2/2014)

*To be included on the www.LearningHealth.org website.
Core Values Underlying a National-Scale Person-Centered Continuous Learning Health System (LHS)

Preamble

The national-scale, person-centered, continuous and rapid learning health system (LHS) will improve the health of individuals and populations. The LHS will accomplish this by generating information and knowledge from data captured and updated over time—as an ongoing and natural by-product of contributions by individuals, care delivery systems, public health programs, and clinical research—and sharing and disseminating what is learned in timely and actionable forms that directly enable individuals, clinicians, and public health entities to separately and collaboratively make informed health decisions.

The proximal goal of the LHS is to efficiently and equitably serve the learning needs of all participants, as well as the overall public good. The LHS offers an important opportunity to facilitate sharing of data in order to serve this goal, aiming to surmount obstacles to such sharing.

The LHS will develop as a synergy of initiatives already underway, as well as new ones that will be launched, by creating an environment that fosters collaboration and harmonization among all stakeholders. It is anticipated that the LHS, in its operation, will leverage a data federation rather than a centralized national database. The LHS will build upon enablers already taking shape, including the national pursuit of Meaningful Use of electronic health records, personal health records, and other health information technologies. Ultimately recognizing that better health for all is a global imperative, the LHS aspires to embrace strategic approaches that facilitate harmonization with other nations in pursuit of a global system, as well as within the United States.

Core Values

The design and operation of the national-scale LHS derive from its core values:

1. Person-Focused: The LHS will protect and improve the health of individuals by informing choices about health and healthcare. The LHS will do this by enabling strategies that engage individuals, families, groups, communities, and the general population, as well as the United States healthcare system as a whole.

2. Privacy: The LHS will protect the privacy, confidentiality, and security of all data to enable responsible sharing of data, information, and knowledge, as well as to build trust among all stakeholders.

3. Inclusiveness: Every individual and organization committed to improving the health of individuals, communities, and diverse populations, who abides by the governance of the LHS, is invited and encouraged to participate.
4. **Transparency**: With a commitment to integrity, all aspects of LHS operations will be open and transparent to safeguard and deepen the trust of all stakeholders in the system, as well as to foster accountability.

5. **Accessibility**: All should benefit from the public good derived from the LHS. Therefore, the LHS should be available and should deliver value to all, while encouraging and incentivizing broad and sustained participation.

6. **Adaptability**: The LHS will be designed to enable iterative, rapid adaptation and incremental evolution to meet current and future needs of stakeholders.

7. **Governance**: The LHS will have that governance which is necessary to support its sustainable operation, to set required standards, to build and maintain trust on the part of all stakeholders, and to stimulate ongoing innovation.

8. **Cooperative and Participatory Leadership**: The leadership of the LHS will be a multi-stakeholder collaboration across the public and private sectors including patients, consumers, caregivers, and families, in addition to other stakeholders. Diverse communities and populations will be represented. Bold leadership and strong user participation are essential keys to unlocking the potential of the LHS.

9. **Scientific Integrity**: The LHS and its participants will share a commitment to the most rigorous application of science to ensure the validity and credibility of findings, and the open sharing and integration of new knowledge in a timely and responsible manner.

10. **Value**: The LHS will support learning activities that can serve to optimize both the quality and affordability of healthcare. The LHS will be efficient and seek to minimize financial, logistical, and other burdens associated with participation.
Learning Health Community
ATTN: Joshua C. Rubin
901 North Pollard Street, #1107
Arlington, VA 22203

Dear Mr. Rubin:

Via this letter, <organization name> formally indicates its endorsement of the Learning Health System (LHS) Core Values, as expressed in the document of that name dated July 20, 2012.

<organization name> endorses these Core Values to express to its support for the concept of a national-scale LHS, and to express its belief that these values are foundational to a successful, multi-stakeholder process to advance the nation toward an LHS in pursuit of better health for all.

This endorsement does not commit <organization name> to participation in any specific activity, nor does it commit any resources on the part of <organization name>. This endorsement does authorize the inclusion of <organization name’s> name on a public website that will list all organizations that have endorsed the Core Values, as well as in a one-time press release. Any other use of <organization name’s> name in connection with this endorsement will require specific advance permission.

This endorsement may be withdrawn at any time.

SIGNATURE LINES
January 22, 2013

Dear Colleague:

I am writing to invite you and your organization to support healthcare transformation by joining a multi-stakeholder movement to develop a national learning health system (LHS).

The learning health system (LHS) will support the transformation of American healthcare to which we are all committed, enabling us to learn more rapidly from the increasing amounts of digitally stored health information—to help individuals make better-informed care decisions, to improve patient care, and to support public health and biomedical research.

A collaborative, grassroots approach to building a national learning health system is growing out of the May, 2012 LHS Summit sponsored by the Joseph H. Kanter Family Foundation. At the Summit, over 80 organizations spanning the health sector worked together to develop a set of LHS Core Values (attached). I am proud that Geisinger is one of the 36 organizations that have formally endorsed the Core Values and is an active member of the Learning Health Community (http://www.learninghealth.org) that has grown out of it.

Please review the attached Core Values and consider endorsing them using the attached endorsement template. Endorsing these Core Values will make an important statement and link your organization with a growing network of like-minded organizations. (Your endorsement does not commit your organization to support the Learning Health Community in any way.)

Additional information can be found in the attached article, the reports from the Institute of Medicine (IOM) reports listed below, and the Federal Health IT Strategic Plan, also listed below. Please direct specific questions about the Learning Health Community and the endorsement process to Josh Rubin, Executive Director of the Joseph H. Kanter Family Foundation, at Josh@JoshCRubin.com.

Sincerely,

Glenn D. Steele, Jr., MD, PhD
President & Chief Executive Officer

Attachments
HIMSS Supports National-Scale Learning Health System’s Core Values

Release Date:
Monday, September 24, 2012 9:00 am CDT

Terms:
Dateline City:
Chicago

Joining more than 40 organizations, HIMSS endorses the 10 core values of a Learning Health System, supporting a collaborative effort to share data, enable learning and improve the health of individuals and populations.

At its September 14, 2012 meeting in Washington, DC, the HIMSS Board of Directors confirmed its endorsement of the core values of a Learning Health System. With this data-sharing federation, individuals, care delivery systems, public health programs and clinical research settings will contribute data that can be shared in timely and actionable formats to help patients, caregivers and others make informed health decisions, separately or collaboratively.

These core values were developed at the Learning Health System Summit, convened by the Joseph E. Kanter Family Foundation, from May 17-18, 2012, in Washington, DC, where representatives from 80 organizations gathered to review and discuss the future of the LHS. As noted in its letter to the Kanter foundation, “HIMSS endorses these core values to express its support for the concept of a national-scale LHS, and to express its belief that these values are foundational to a successful, multi-stakeholder process to advance the nation toward an LHS in pursuit of better health for all.”

This HIMSS endorsement comes following the release of the groundbreaking Institute of Medicine Report Better Care at Lower Cost. The report indicts the American healthcare system as wasteful and dangerous, citing an estimated $750 billion dollars in waste in 2009 and 75,000 needless deaths in 2005.

In addition, the report makes recommendations for improving digital infrastructure, achieving care coordination, making care patient centric, improving transparency, and structuring payment to incentivize continuous learning. These recommendations are designed to transform the current health care system through the use of tools and incentives for continuous assessment and improvement.

“The 10 core values for the proposed Learning Health System and recommendations in the IOM report (Better Care at Lower Cost) also closely align with many of our policy principles and overall cause to improve healthcare with the best use of IT,” says H. Stephen Lieber, CAE, HIMSS President and CEO. Lieber also cited case studies from HIMSS Davies Award winners and Stage 7 hospitals showing how information technology, and patient-centric and coordinated care, improves healthcare delivery and reduces costs. “The LHS will provide options for anyone seeking research information on quality care and preventive care. This multi-stakeholder approach will streamline the process to identify and gather data so that they are accessible in a secure way to anyone who can benefit from their use.”

A learning health care system generates and applies the best evidence for the collaborative health care choices of each patient and provider; drives the process of discovery as a natural outgrowth of patient care; and ensures innovation, quality, safety, and value in health care. In such a system, knowledge flows seamlessly between and among patients, providers, diagnostic facilities, and related community services. The best knowledge about treatments, diagnostics, and care delivery is naturally embedded in the delivery process, and new knowledge is captured as an integral by-product of the delivery experience.

Source: Better Care at Lower Cost, Institute of Medicine, September 2012

As an example of what an LHS could do, the IOM report states that “…advances in patient engagement take on increased
As an example of what an LHS could do, the IOM report states that “…advances in patient engagement take on increased importance as a means of ensuring that patients can find the right care for their individual characteristics, needs, preferences, and circumstances. Patients and clinicians both need to be involved for optimal care. Clinicians supply information and advice based on their scientific expertise in treatment and intervention options. Patients, their families, and other caregivers bring personal knowledge on the suitability of different treatments for the patient’s circumstances and preferences. Information from both sources is needed to select the right care options.”

The core values for the Learning Health System and developed by participating attendees at the Learning Health System Summit follow.

**Person-Focused:** The LHS will protect and improve the health of individuals by informing choices about health and healthcare. The LHS will do this by enabling strategies that engage individuals, families, groups, communities, and the general population, as well as the United States healthcare system as a whole.

**Privacy:** The LHS will protect the privacy, confidentiality, and security of all data to enable responsible sharing of data, information, and knowledge, as well as to build trust among all stakeholders.

**Inclusiveness:** Every individual and organization committed to improving the health of individuals, communities, and diverse populations, who abides by the governance of the LHS, is invited and encouraged to participate.

**Transparency:** With a commitment to integrity, all aspects of LHS operations will be open and transparent to safeguard and deepen the trust of all stakeholders in the system, as well as to foster accountability.

**Accessibility:** All should benefit from the public good derived from the LHS. Therefore, the LHS should be available and should deliver value to all, while encouraging and incentivizing broad and sustained participation.

**Adaptability:** The LHS will be designed to enable iterative, rapid adaptation and incremental evolution to meet current and future needs of stakeholders.

**Governance:** The LHS will have that governance which is necessary to support its sustainable operation, to set required standards, to build and maintain trust on the part of all stakeholders, and to stimulate ongoing innovation.

**Cooperative and Participatory Leadership:** The leadership of the LHS will be a multi-stakeholder collaboration across the public and private sectors including patients, consumers, caregivers, and families, in addition to other stakeholders. Diverse communities and populations will be represented. Bold leadership and strong user participation are essential keys to unlocking the potential of the LHS.

**Scientific Integrity:** The LHS and its participants will share a commitment to the most rigorous application of science to ensure the validity and credibility of findings, and the open sharing and integration of new knowledge in a timely and responsible manner.

**Value:** The LHS will support learning activities that can serve to optimize both the quality and affordability of healthcare. The LHS will be efficient and seek to minimize financial, logistical, and other burdens associated with participation.

**About HIMSS**

HIMSS is a cause-based, not-for-profit organization exclusively focused on providing global leadership for the optimal use of information technology (IT) and management systems for the betterment of healthcare. Founded 51 years ago, HIMSS and its related organizations are headquartered in Chicago with additional offices in the United States, Europe and Asia. HIMSS represents more than 44,000 individual members, of which more than two thirds work in healthcare provider, governmental and not-for-profit organizations. HIMSS also includes over 570 corporate members and more than 170 not-for-profit organizations that share our mission of transforming healthcare through the effective use of information technology and management systems. HIMSS frames and leads healthcare practices and public policy through its content expertise, professional development, research initiatives, and media vehicles designed to promote information and management systems’ contributions to improving the quality, safety, access, and cost-effectiveness of patient care. To learn more about HIMSS and to find out how to join us and our members in advancing our cause, please visit our website at [www.himss.org](http://www.himss.org).

**Language:**

English

**Contacts:**

[Joyce Lofstrom](http://press.himss.org/node/32)


**Links:**

Joseph H. Kanter Family Foundation Convenes Historic Learning Health System Summit; Stakeholders Collaboratively Work Toward Realizing a National-Scale Learning Health System

Washington, D.C. – The Joseph H. Kanter Family Foundation (KFF) convened a two-day Learning Health System (LHS) Summit on May 17 and 18 where over 80 prominent individuals representing organizations and stakeholders across the health care and health IT communities gathered at The National Press Club in Washington, D.C. Participants worked together to begin laying key foundational elements that promise to harmonize and coalesce cutting-edge work presently underway into a national-scale LHS.

A multi-stakeholder, 16-member Planning Committee, including two former United States National Coordinators for Health Information Technology (Dr. David Blumenthal who served under a Democratic administration and Dr. Robert Kolodner who served under a Republican administration), has been working for the past half-year to plan the Summit. The Planning Committee played an instrumental role in identifying participants to be invited and organizations to be represented at this limited-capacity, invitation-only Summit.

Utilizing a definition developed by the Institute of Medicine (IOM), a “Learning Health System” is defined as “one in which progress in science, informatics, and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience, and seamlessly refine and deliver best practices for continuous improvement in health and health care.” Achievement of a national-scale LHS will improve health care quality by streamlining research, by supporting public health, by advancing patient safety, and by empowering clinicians and patients alike to make better-informed health decisions through enabling investigators to study what works best for every disease for every patient. Through a learning system, new biomedical knowledge will find its way very quickly into health care.

Participants in the two-day Summit began working toward achieving multi-stakeholder consensus on a set of principles that would underlie the development of a national-scale LHS benefiting stakeholders across the health care spectrum. In certain respects, the Summit was modeled after the 1944 Dumbarton Oaks Conference where a critical mass of key world leaders convened to achieve consensus around principles that ultimately served as the foundation upon which the United Nations was built; the Summit aspires to be to the creation a national-scale LHS what the Dumbarton Oaks Conference was to the founding of the United Nations.

KFF Chairman Joe Kanter framed the two-day summit by asking two critical questions of all participants: 1.) What can a Learning Health System do for you?
And 2.) What can you do for a Learning Health System?

“KFF sponsored the Summit because our nation’s health care system is facing a grave crisis and the time for action is now,” said health care pioneer and prostate cancer survivor Joe Kanter, who is the namesake of the foundation. “A special kind of leadership is required to foster an environment where stakeholders can work together to harmonize and synergize efforts currently underway to collectively build a national-scale LHS. Such leadership must facilitate the development of a national-scale LHS not by controlling, but by stimulating creativity and innovation, as well as providing simple and trustworthy governance.” Paying tribute to the Summit’s historical significance, Kanter concluded, “The efforts of Summit participants collectively represent one of our nation’s great feats in health care by engaging such an impressive and diverse group working together in a collaborative and bi-partisan manner to give the gift of health to our children and our nation.”

“I am struck that we may have started something transcendent. I do not believe that, in the history of health in the United States, a multi-stakeholder group like this has ever gathered around an issue of such importance and common interest,” said Dr. Charles Friedman, director of the Health Informatics program at the University of Michigan, who chaired the Planning Committee.

The Summit generated significant enthusiasm. Recognizing the urgency of harnessing this momentum, KFF Executive Director Josh Rubin stated that, “Key next steps include continuing the consensus process around the principles and working to create a Learning Health Community. This community will develop bottom-up as a coalition of the willing. Its collaborative work ultimately aims to spawn a series of activities catalyzing the rapid development of a national-scale LHS that promises to empower individuals to transform health care and health.”

Summit participants represented organizations and stakeholder groups including: patient advocacy and consumer organizations, provider organizations, research organizations, government agencies, payers, clinicians, the pharmaceutical industry, health IT vendors, philanthropic organizations, professional associations, research initiatives and organizations, and thought leaders. For a complete list of participating individuals and the organizations they respectively represented, please see http://kanterhealth.org/featured/2012-summit/.

Joseph H. Kanter Family Foundation: http://kanterhealth.org
The Joseph H. Kanter Family Foundation and Health Legacy Partnership, a non-profit organization based in Washington D.C., aims to effectuate a health system that leverages the power of health information technology (HIT) and electronic health records (EHRs) to learn from real-world patient experiences by putting patients at its center.

##
This is the News

CDISC Launches Learning Health Community Standards Initiative

March 7, 2013

Austin, TX – 7 March 2013 - The Clinical Data Interchange Standards Consortium (CDISC) organized and hosted a meeting in Austin, TX to launch the Essential Standards to Enable Learning (ESTEL) initiative of the Learning Health Community (LHC). The CDISC-led ESTEL initiative is the first of several that have grown out of the May 2012 Learning Health System (LHS) Summit, sponsored by the Joseph H. Kanter Family Foundation (KFF), which convened a critical mass of key stakeholders representing over 80 organizations across the healthcare spectrum and achieved multi-stakeholder consensus on a set of ten LHS Core Values that will underpin a national-scale LHS. Such consensus has given rise to the self-organizing (and ever-growing) Learning Health Community bonded together by a shared belief in the Core Values and a common drive to work collaboratively to transform healthcare and health by realizing an LHS. A key goal of a Learning Health System (LHS) is to significantly shorten the time by which clinical research results inform clinical care decisions to improve the lives of patients.

The ESTEL initiative of the LHC was launched by CDISC specifically to concentrate on the identification of a minimal set of standards to enable an LHS. The meeting was attended by experts from the U.S. and Argentina, representing universities, clinical research organizations, technology companies, service providers, standards developing organizations and government (HHS/ONC). LHS use cases were developed to lead to the creation of a minimal set of standards and examples of how an LHS should work. “The participation in this LHS ESTEL Launch was impressive” stated Rebecca Kush, CDISC President and CEO. “Leaders in the Health IT and eHealth arenas came together to solve a very real problem for patients today, and they signed on to be responsible for action steps to move this initiative forward.”

CDISC will be hosting a webinar on 14 March 2013 to review the ESTEL meeting outcomes in detail. To attend, please register through this link: https://www1.gotomeeting.com/register/811535160

At the close of the ESTEL meeting, Joshua Rubin of KFF described himself as "awe struck" by the progress made. "The scale and scope of the transformation we are seeking to effectuate is beyond what any one organization or even stakeholder group can do alone. What we have done together then, is to transform our individual and collective efforts and passions into an emerging national, and one day global movement," Rubin stated.
ABOUT CDISC

CDISC is a 501(c)(3) global non-profit charitable organization, with over 300 supporting member organizations from across the clinical research and healthcare arenas. Through the efforts of volunteers around the globe, CDISC catalyzes productive collaboration to develop industry-wide data standards enabling the harmonization of clinical data and streamlining research processes from protocol through analysis and reporting, including the use of electronic health records to facilitate the collection of high quality research data. The CDISC standards and innovations can significantly decrease the time and cost of medical research and improve data quality, thus contributing to the faster development of safer and more effective medical products and a learning healthcare system. The CDISC Vision is to inform patient care and safety through higher quality medical research.
Learning Health Community Launches Multi-Stakeholder Initiative to Develop LHS Policy and Governance Framework

November 12, 2014

Research Triangle Park, NC – On October 27, 2014, over two dozen multi-stakeholder thought leaders spanning the health IT, health policy, and health care arenas gathered to discuss a policy and governance framework for a national-scale (and ultimately global) Learning Health System (LHS). The North Carolina Healthcare Information and Communications Alliance, Inc. (NCHICA) hosted the meeting, which marked the launch of the LHS governance initiative of the Learning Health Community.

The multi-stakeholder Learning Health Community (www.LearningHealth.org) itself grew out of the groundbreaking 2012 LHS Summit in Washington, DC, sponsored by the Joseph H. Kanter Family Foundation. Members of the Community have a shared belief in the LHS Core Values (http://www.learninghealth.org/about-the-community/) developed by the LHS Summit’s over 80 participants representing organizations spanning the health spectrum.

According to Dr. Charles Friedman, Community Interim Steering Committee chair, “In the LHS, we will harness the power of data and analytics to learn from the experiences of large numbers of individuals and feed the knowledge and learning generated of ‘what works best’ back to all stakeholders to improve the health of individuals and populations.” The LHS concept gained increasing attention as a result of a series of Institute of Medicine (IOM) workshops and related reports beginning in 2007 (http://iom.edu/~/media/Files/Activity%20Files/Quality/VSRT/Core%20Documents/LearningHealthSystem.pdf).

Widespread support for the vision is seen in federal grants, ongoing patient advocacy initiatives, journal publications, and the birth of a multi-stakeholder grassroots coalition (www.LearningHealth.org/endorsers) working to achieve individual, public and population health and healthcare improvements. Envisioning the LHS as a paradigm, participants noted that the LHS can transform healthcare and health the way the Internet has transformed commerce and communication. Josh Rubin, JD, who serves on the Community’s Interim Steering Committee, noted, “When successful, the policy and governance framework will facilitate and incentivize an optimal level of trust and collaboration to drive continuous innovation, ultimately helping the lives and improving the health of current and future generations.”

Holt Anderson, who served as NCHICA’s Executive Director for nearly two decades, and is now focusing his efforts on leading the LHS policy and governance framework task initiative,
commented, “there has been a lot of discussion and a degree of consensus built that a LHS will improve care based on treatment of individuals and populations with similar conditions, and what is needed now to move us forward is action – guided by a roadmap that participants can agree on.” Participants at the October 27th meeting organized into task forces that will identify concrete deliverables, engage additional interested parties, and develop timelines and project plans for moving their work forward. NCHICA will facilitate continued collaboration among the task forces.

Rubin noted further, “achieving an operational LHS is too big and audacious a project for any one organization or group to undertake alone and it will only ultimately work for everyone if we all realize it together.”

About NCHICA

The North Carolina Healthcare Information and Communications Alliance, Inc. (NCHICA) is a nonprofit consortium dedicated to assisting NCHICA members in accelerating the transformation of the United States healthcare system through the effective use of information technology, informatics, and analytics. Members include leading organizations in healthcare, research and information technology. For more information, please visit: www.nchica.org.

About the Learning Health Community

The mission of the Learning Health Community is to serve as the center of collaboration, intelligence, and action to lead and galvanize a grassroots movement in which multiple and diverse stakeholders work together to transform healthcare and health by collaboratively realizing a national-scale (and ultimately global) person-centered, continuous and rapid learning health system (LHS). The vision for the LHS is embodied in the consensus LHS Core Values that have been formally endorsed to date by over 60 organizations spanning the health spectrum. Over 1,000 individuals are involved in various capacities in this ever-growing movement. For more information, please visit: www.LearningHealth.org.
State of the Industry: A Grassroots Movement Is Underway to Realize a Nationwide Learning Healthcare System

April 8, 2013

By Charles P. Friedman, PhD; and Joshua C. Rubin, JD, MBA, MPH, MPP

April 2013, HIMSS Clinical Informatics Insights

As the nation’s health system goes digital, a clear consensus is emerging: Our historic investment of over $150 billion in health IT will yield the anticipated benefits only if we harmonize efforts nationwide into a national-scale Learning Healthcare System (LHS). Just as the internet had transformative impacts on numerous and diverse stakeholders’ ways of working, communicating and interacting, the LHS promises to have broad and far-reaching impacts on health.

What is the Learning Healthcare System?
The IOM defines an LHS as “... one in which progress in science, informatics, and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience, and seamlessly refine and deliver best practices for continuous improvement in health and healthcare.”
The LHS is one infrastructure, serving multiple purposes, being built collaboratively atop a foundation of meaningful use and other health IT investments. The LHS allows the increasing amount of health data that is captured digitally — about 30 percent now, expected to be 80 percent by 2019 — to be aggregated, analyzed and converted to actionable knowledge.

This knowledge is then shared with stakeholders who can benefit and learn from it. The LHS holds the potential to transform care delivery by shortening the 17-year gap between knowledge generation and its application, to empower clinicians and patients with knowledge to inform their decisions, and to create a more robust public health and biomedical research infrastructure for the nation.

What is the Learning Healthcare Community Movement?
At the same time, this imperative is spawning a national movement: a grassroots Learning Healthcare Community mobilizing multiple and diverse stakeholders to realize a shared vision for the LHS. This vision was articulated in a set of Core Values developed collaboratively at a multi-stakeholder meeting last May. Noting their alignment with HIMSS’ mission, HIMSS was an early endorser of the LHS Core Values.
The LHS is being realized by initiatives growing out of the Learning Health Community, and, like any grassroots endeavor, it will become what the members of this community make it into. To help give shape to the LHS, we encourage your active participation and invite you to contact the authors to become engaged.

Evidence of support for the Learning Healthcare System
The LHS imperative is supported by a series of reports by the Institute of Medicine (IOM), the Federal Health IT Strategic Plan: 2011-2015, an issue of Health Affairs dedicated to rapid learning, and a recent New England Journal of Medicine commentary.

About the Contributors
Charles P. Friedman, PhD, is the Professor of Information and Public Health at the University of Michigan. Joshua C. Rubin, JD, MBA, MPH, MPP, is Executive Director of the Joseph H. Kanter Family Foundation.
Weaving Together A HEALTHCARE Improvement Tapestry

LEARNING HEALTH SYSTEM BRINGS TOGETHER HEALTH IT DATA STAKEHOLDERS TO SHARE KNOWLEDGE AND IMPROVE HEALTH

By Joshua C. Rubin, JD, MBA, MPH, MPP, and Charles P. Friedman, PhD
As the “VISION” section of AHIMA’s website states, AHIMA aims to “lead the advancement and ethical use of quality health information to promote health and wellness worldwide.” In many ways, the Learning Health System’s (LHS) overarching vision represents what can happen when diverse stakeholders connect and harmonize efforts at multiple levels to do just that. The LHS vision can, in many ways, serve the learning needs of all healthcare stakeholders. Many feel the LHS is urgently needed to foster a cyber-social transformation of healthcare—transformation needed at a magnitude that can only be realized by multiple and diverse stakeholders working together toward achieving a shared vision. The vision of the LHS is being realized, in part, through a grassroots movement known as the Learning Health Community, which is currently under way.

The LHS can be seen as the tapestry that emerges from weaving together efforts across the health information management, health IT, patient engagement, clinical care, research, and public health arenas aimed at utilizing data, information, and knowledge to improve health. In its 2011 “Digital Infrastructure for the Learning Health System” report, the Institute of Medicine (IOM) defined the LHS as a system “in which progress in science, informatics, and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience, and seamlessly refine and deliver best practices for continuous improvement in health and healthcare.” Understanding the transformative potential of a system that optimizes every participant’s ability to learn from the ever-increasing amount of digitally captured health data, patient activist Regina Holliday in 2012 described a key component of the LHS vision by asking, “What if your data did not have to die in dusty paper files and unconnected electronic silos? What if many private institutions, non-profit organizations, research centers, government entities and individual patients decided to share data? What if we could do this over a span of years creating an ever larger data set? That data set could be accessed by the many in a timely fashion that will enable both the individual and the organization to make informed health decisions.”

LHS Use Cases Illustrate Transformative Potential

The LHS will, as a single infrastructure producing cycles of learning and continuous improvement on many scales, serve the learning needs of all stakeholders—empowering them to take actions informed by this timely-generated knowledge, and bringing about transformative change.

Several sample use cases serve to illuminate the potential of an LHS:

- When a patient faces a difficult medical decision, in collaboration with clinicians, the patient will be able to base that decision on the real world experiences of similar patients. Such informed decision-making is rendered possible precisely because the data describing those experiences do not die in paper files or electronic silos and remains available as a learning resource for others.
- A stakeholder interested in post-market surveillance of a new drug will be able to rapidly detect safety signals and recognize the imperative to modify personalized dosage algorithms. This detection will come directly from electronic health record (EHR) data captured as a byproduct of care delivery, as well as other sources. In turn, modified clinical decision support rules based on these personalized dosage algorithms can be rapidly created and fed into EHR systems.
- During an epidemic public health stakeholders will be able to receive near real-time reports of new cases. Rapid analysis based on this quick, systematic reporting will enable clinicians to be alerted as the disease spreads to new geographic areas.
- Multiple and diverse stakeholders with shared interests in developing innovative solutions to address important health and healthcare challenges will be empowered to utilize the same infrastructure that enables the previously described use cases to also serve as a foundation upon which to develop and iteratively refine as-yet unimagined innovations aimed at realizing transformative impacts.

Why the LHS is Urgently Needed

Single-purpose initiatives aimed at learning from real world experiences of patients captured as a byproduct of care delivery illuminate the potential impact of such learning when it is made routine and empowered to occur at a large scale. According to the National Cancer Institute (NCI), since the 1970s significant portions—presently around 4,000 children in NCI-sponsored trials alone—of the approximately 10,000 children per year diagnosed with cancer have entered clinical trials. With such a high rate of participation and large data field to study, the United States has been able to greatly improve and tailor treatments and survival rates for childhood cancers. Treatment has improved dramatically.

The American Childhood Cancer Organization has found that in 1977, five-year survival rates hovered around 50 percent. By
could draw on data from every patient’s experience across the patients, in under six months in a system of 150 million patients, in half that time in a learning system of seven to eight million treatments that do not work.

2007 that figure rose to 80 percent, a 60 percent improvement during the time period. On a smaller, personalized medicine scale, pediatrician informaticists at a prominent children’s hospital recently found themselves in a situation treating a 13-year-old girl with lupus and other comorbidities where “there aren’t even meager data available and we don’t have a single anecdote on which to draw,” the informaticists were quoted as writing in the New England Journal of Medicine. The team took an approach where, “Without clear evidence to guide us and needing to make a decision swiftly, we turned to a new approach, using the data captured in our institution’s electronic medical record (EMR) and an innovative research data warehouse...” This was a rapid learning approach from the best available data, and was a move that likely saved the patient’s life.

With such potential illuminated, it is worth noting that many of the most transformative types of learning can only occur at a larger scale. As one research team who used a large UK database to demonstrate the potential to learn valid lessons from real world data noted, “On the basis of our work to date, we estimate that 40-50 million patients are needed for the breadth of future studies we can envisage.” Similarly, looking at drug safety surveillance, Dr. Larry Norton of Memorial Sloan Kettering Cancer Center estimated that the safety signal detection that actually took over five years to develop could have been accomplished in half that time in a learning system of seven to eight million patients, in under six months in a system of 150 million patients, and in a mere eight to 10 weeks if safety surveillance systems could draw on data from every patient’s experience across the United States.

LHS Could Cure Many Current Healthcare Ailments

With that said, such routine, systemic learning is the exception rather than the rule in healthcare today. There is an argument to be made that a number of challenges that continue to plague our healthcare system overall are symptoms of a deeper problem that payment reform and even care coordination measures cannot address alone. Though the United States healthcare system attracts dedicated, bright, caring, innovative, and hard-working clinicians, researchers, administrators, and public health professionals, the present system’s inability to learn routinely—and at scale—from most experiences directly or indirectly relates to the following symptoms, and more:

- **Not self-improving.** Even though cancer has remained the number two cause of mortality for the past 75 years, the American Society of Clinical Oncology notes that fewer than three percent of adult cancer patients participate in clinical trials; no systematic learning results are available from over 97 percent of these patients’ experiences.

- **Wasteful and inefficient.** According to the IOM’s 2012 “Best Care at Lower Cost: The Path to Continuous Learning Health Care in America” report, up to $750 billion annually—a figure that by itself is larger than all but 18 countries’ GDPs, or 30 cents of every healthcare dollar—is wasted on administrative inefficiencies, fraud, abuse, and treatments that do not work.

- **Unsafe.** Over a decade ago, the IOM’s landmark “To Err is Human” report estimated that 44,000 to 98,000 Americans die every year in hospitals alone due to preventable medical errors. A 2013 study titled “A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care,” published in the Journal of Patient Safety, places the figure at 210,000 to over 400,000 deaths. This would render preventable medical errors in hospitals the number three leading cause of mortality, behind cancer and heart disease.

- **Inaccurate.** According to a 2012 study published in the Journal of the American Medical Association titled, “Bringing Diagnosis Into the Quality and Safety Equations,” between 10 and 20 percent of diagnoses are delayed or wrong. Another previously published study, “Diagnostic Error in Medicine: Analysis of 583 Physician-Reported Errors,” suggested that over a quarter of incorrect diagnoses contribute to outcomes that prove to be life-threatening or lead to permanent disability—yet the health system does not learn routinely so that it can improve.

- **Inconsistent.** As a former CEO of a major pharmaceutical company stated in a 2008 interview, “Efficacy rates of medicines prescribed for some of the most common illnesses average around 50 percent. That means some are more effective than 50 percent, but some are far less. Drugs for reducing cholesterol, for instance, work about 80 percent of the time... while many cancer drugs are only 20 percent effective.” Indeed, according to Foundation for the National Institutes of Health research underpinning the I-SPY 2 trial, “most breast cancer drugs work for only 30 to 50 percent of the patients for whom they are prescribed, and developing each drug typically takes many years, involves thousands of patients and costs well over $1 billion.” That findings of pre-clinical research studies in areas such as cancer care so often cannot be replicated, as documented in a commentary in Nature titled “Drug Development: Raise Standards for Preclinical Cancer Research,” only compounds these types of issues. Further, a 2003 study published in the New England Journal of Medicine titled “The Quality of Health Care Delivered to Adults in the United States” provided evidence indicating that patients do not receive over 45 percent of recommended care.

- **Lethally slow to improve.** The commonly cited 17-year gap between knowledge generation and its application in practice is not the only way our healthcare system can be lethally slow. Roughly 75,000 deaths per year could be averted if every state delivered care at the quality level of the best performing state, according to the previously mentioned 2012 IOM report “Best Care at Lower Cost.” But knowledge and practices requisite to do so are disseminated at a lethally slow rate. Analysis of quality measures over the years by Dr. William Stead of Vanderbilt University Medical Center, which included those published in various Agency for Healthcare Research and Quality
Lacking information. Even with the extensive training clinicians’ experience, a wealth of knowledge does not systematically make its way into the hands of clinicians, patients, and other stakeholders when they need it. As documented in Wired UK in a 2013 piece titled “IBM’s Watson is Better at Diagnosing Cancer than Human Doctors,” research by IBM and Memorial Sloan-Kettering Cancer Center demonstrates that only around 20 percent of the information doctors use to inform diagnosis and treatment recommendations is trial evidence-based. At the rate at which new medical information is generated, as described in the international collaborative Organisation for Economic Co-operation and Development (OECD) report “Health at a Glance 2013: OECD Indicators,” the United States was shown to spend more than twice as much on healthcare per capita as many other OECD countries that surpass the United States in vital health outcome measures, such as life expectancy at birth and infant mortality. A 2012 press release by The Commonwealth Fund, appropriately titled “U.S. Spends Far More for Health Care Than 12 Industrialized Nations, but Quality Varies,” found that “the U.S. spent nearly $8,000 per person in 2009 on health care services, while other countries in the study spent between one-third (Japan and New Zealand) and two-thirds (Norway and Switzerland) as much. While the US performs well on breast and colorectal cancer survival rates, it has among the highest rates of potentially preventable deaths from asthma and amputations due to diabetes and rates that are no better than average for in-hospital deaths from heart attack and stroke.” While these statistics cannot be as directly connected to a lack of learning as others previously cited (because the comparison countries also do not learn systematically and rapidly), they nonetheless underscore the urgency of change, especially in a country where healthcare currently represents 18 percent of GDP and, by some projections—as cited by White House officials in “The Economic Case for Health Care Reform”—could almost double that share by 2040.

Blind. Our healthcare system cannot monitor itself in real time. A USA Today story from almost a decade ago, for instance, describes a study on a database of Kaiser Permanente members that showed four years after the release of a popular drug, taken by two million Americans at the time, was linked to over 27,000 heart attacks and sudden cardiac deaths nationwide. The drug was not pulled from the market until more than five years after its release. Had the healthcare industry been able to monitor in real-time the spike in heart attacks associated with this drug’s use, it would have presented a safety signal upon which providers could have acted years earlier, perhaps saving many of those lives.

Expensive. As documented in the international collaborative Organisation for Economic Co-operation and Development (OECD) report “Health at a Glance 2013: OECD Indicators,” the United States was shown to spend more than twice as much on healthcare per capita as many other OECD countries that far surpass the United States in vital health outcome measures, such as life expectancy at birth and infant mortality. A 2012 press release by The Commonwealth Fund, appropriately titled “U.S. Spends Far More for Health Care Than 12 Industrialized Nations, but Quality Varies,” found that “the U.S. spent nearly $8,000 per person in 2009 on health care services, while other countries in the study spent between one-third (Japan and New Zealand) and two-thirds (Norway and Switzerland) as much. While the US performs well on breast and colorectal cancer survival rates, it has among the highest rates of potentially preventable deaths from asthma and amputations due to diabetes and rates that are no better than average for in-hospital deaths from heart attack and stroke.” While these statistics cannot be as directly connected to a lack of learning as others previously cited (because the comparison countries also do not learn systematically and rapidly), they nonetheless underscore the urgency of change, especially in a country where healthcare currently represents 18 percent of GDP and, by some projections—as cited by White House officials in “The Economic Case for Health Care Reform”—could almost double that share by 2040.

Learning Health System Core Values

THE DESIGN AND operation of the national-scale LHS derive from the system’s Core Values. The Core Values were developed at the 2012 Learning Health System Summit.

1. **Person-Focused.** The LHS will protect and improve the health of individuals by informing choices about health and healthcare. The LHS will do this by enabling strategies that engage individuals, families, groups, communities, and the general population, as well as the United States healthcare system as a whole.

2. **Privacy.** The LHS will protect the privacy, confidentiality, and security of all data to enable responsible sharing of data, information, and knowledge, as well as to build trust among all stakeholders.

3. **Inclusiveness.** Every individual and organization committed to improving the health of individuals, communities, and diverse populations, who abides by the governance of the LHS, is invited and encouraged to participate.

4. **Transparency.** With a commitment to integrity, all aspects of LHS operations will be open and transparent to safeguard and deepen the trust of all stakeholders in the system, as well as to foster accountability.

5. **Accessibility.** All should benefit from the public good derived from the LHS. Therefore, the LHS should be available and should deliver value to all, while encouraging and incentivizing broad and sustained participation.

6. **Adaptability.** The LHS will be designed to enable iterative, rapid adaptation and incremental evolution to meet current and future needs of stakeholders.

7. **Governance.** The LHS will promote governance, which is necessary to support its sustainable operation, to set required standards, to build and maintain trust on the part of all stakeholders, and to stimulate ongoing innovation.

8. **Cooperative and Participatory Leadership.** The leadership of the LHS will be a multi-stakeholder collaboration across the public and private sectors including patients, consumers, caregivers, and families, in addition to other stakeholders. Diverse communities and populations will be represented. Bold leadership and strong user participation are essential keys to unlocking the potential of the LHS.

9. **Scientific Integrity.** The LHS and its participants will share a commitment to the most rigorous application of science to ensure the validity and credibility of findings, and the open sharing and integration of new knowledge in a timely and responsible manner.

10. **Value.** The LHS will support learning activities that can serve to optimize both the quality and affordability of healthcare. The LHS will be efficient and seek to minimize financial, logistical, and other burdens associated with participation.
Health Community is emerging to shape these activities into LHS challenge, a grassroots movement called the Learning With work under way to address disparate components of the Grows to Bring It All Together

Grassroots Learning Health Community Movement cannot learn routinely and at scale, and highlight the transfor-
mative potential of empowering all stakeholders in the health-
care spectrum to do so. This imperative has been evidenced in a series of IOM reports and was the single topic discussed in the entire January 2007 issue of Health Affairs. Achieving rapid learning as the pinnacle goal was also included in the Federal Health Information Technology Strategic Plan: 2011-2015. In April 2013, HIMSS’ Clinical Informatics Insights devoted an entire issue to the LHS, a New England Journal of Medicine commentary called for realizing a national-scale LHS as a key way to safely reduce healthcare’s GDP footprint, and another commentary urged that “In the Big Data era, (Academic Health Centers) should strive to become ‘learning health systems.” This year kicked off with a Journal of the American Medical Association viewpoint piece, appropriately titled “A Learning Health Care System for Pediatrics,” calling for the realization of a pediat-
tric LHS.

Indeed many large health systems are using their ever-in-
creasing amounts of digital health data to become “learning islands,” and are even joining in some collaborative efforts as exemplified by the Care Connectivity Consortium and the HMO Research Network, as well as specific disease-focused efforts epitomized by ASCO’s CancerLinQ. Government and private grants are funding key pieces of the LHS puzzle, perhaps best exemplified by a 2013 National Science Foundation funded workshop aimed at identifying research challenges to be ad-
dressed to realize a high-functioning LHS, and by the number of Patient Centered Outcomes Research Institute (PCORI) clinical data and patient-powered research network awards issued in late 2013 to projects with terms similar to “learning health system” in their titles. These trends highlight the notion that “LHS fever” is infecting all types of interested stakeholders; there is an imperative and a collective motivation to realize the LHS vision.

Grassroots Learning Health Community Movement Grows to Bring It All Together

With work under way to address disparate components of the LHS challenge, a grassroots movement called the Learning Health Community is emerging to shape these activities into a single national-scale LHS. The Learning Health Community aims to mobilize and empower multiple and diverse stakehold-
ers to collaboratively realize a national-scale, and ultimately global-scale, LHS. Models of large-scale, sustained, multi-stake-
holder collaboration that have enabled the development of en-
during and transformative public and private innovations like the United Nations, the VISA credit card network, and the Internet, among others that continue to touch lives around the world and across generations, all informed the planning of the multi-stakeholder activities that catalyzed the organic self-organizing of the Learning Health Community.

The Learning Health Community grew out of a 2012 LHS Sum-
mit sponsored by the Joseph H. Kanter Family Foundation. The LHS Summit brought together a critical mass of key stakeholders spanning healthcare to achieve consensus on a set of 10 LHS Core Values to underpin the development of a national-scale LHS. As of early 2014, 59 prominent organizations with diversity paralleling that of the LHS Summit participants themselves, including AHIMA, have formally endorsed the LHS Core Values. Hundreds of individuals—many prominent leaders inside and outside of healthcare—are lending their time and talents to par-
ticipate in the movement.

The Learning Health Community’s mission is to galvanize a national grassroots movement in which multiple and diverse stakeholders work together to transform healthcare and health by collaboratively realizing the LHS vision. Those participating in the self-organizing efforts of the Learning Health Community are bonded together by their shared determination to realize the LHS and their common belief in the consensus LHS Core Values that serve to underpin it.

The Learning Health Community’s approach is grounded in a collective recognition that the LHS represents an ultra-
large-scale cyber-social system. The LHS is in many respects a challenge that affects more stakeholders and thereby requires greater multi-stakeholder, cross-disciplinary collaboration than does a purely technical challenge such as sending a person to the moon. Indeed, its realization represents a profound socio-
technical challenge as well as an extraordinary and imperative opportunity to effect profound and meaningful health system transformation. Achieving this vision is a challenge too great for any one organization, stakeholder group, or even sector; it can only be achieved through multi-stakeholder, grassroots collabora-
tion.

If the lifeblood of the LHS is shared real world health data and the information and knowledge derived from it, the spirit of the LHS and the Learning Health Community is working together to give the gift of health to our children and our nation. By its grassroots nature, the community is a self-organizing coalition of the willing, whose work is driven by efforts of the participants that grow in the community’s fertile environment conducive to the multi-stakeholder collaboration essential to realizing the LHS as a movement. Consistent with the emergent characteris-
tics of the LHS itself and the grassroots approach of the Learning Health Community, major steps toward realizing the LHS vision...
will be accomplished through self-organizing, multi-stakeholder, collaborative initiatives. Each initiative will be hosted by a trusted neutral convener.

A self-organizing initiative aimed at collaboratively developing and building multi-stakeholder consensus around the LHS governance models, the public health component, and technology to empower stakeholders to harmonize current and future efforts underway across our nation and around the world into an LHS. As a force for health, the community’s efforts have helped to increasingly sustain and grow the presence of LHS-focused work at prominent health IT, public health, health law, health policy, and patient engagement meetings across the nation, and has even brought this grassroots work to the attention of those overseas.

While the fusion of great ideas, insights, and interests from seemingly divergent disciplines and multiple and diverse stakeholders can be more challenging than fission (splitting apart), it is also far more powerful. The community, anchored in the LHS Core Values, is actively working to inspire and catalyze the grassroots collaboration required to harmonize the great work taking shape into the LHS vision that can deliver on its promise to transform healthcare.

The Learning Health Community recognizes that LHS will be a foundation for continuous improvement in healthcare that touches the lives and health of current and future generations across the US and around the world—but only if healthcare stakeholders achieve it together. Like any grassroots endeavor, the Learning Health Community and the initiatives it spawns will become what the members of this community make it into.

To help give shape to the LHS, the authors of this article encourage your active participation and invite you to contact them to become engaged in the movement.

Notes


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Toward a science of learning systems: a research agenda for the high-functioning Learning Health System

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ABSTRACT

Objective The capability to share data, and harness its potential to generate knowledge rapidly and inform decisions, can have transformative effects that improve health. The infrastructure to achieve this goal at scale—marrying technology, process, and policy—is commonly referred to as the Learning Health System (LHS). Achieving an LHS raises numerous scientific challenges.

Materials and methods The National Science Foundation convened an invitational workshop to identify the fundamental scientific and engineering research challenges to achieving a national-scale LHS. The workshop was planned by a 12-member committee and ultimately engaged 45 prominent researchers spanning multiple disciplines over 2 days in Washington, DC on 11–12 April 2013.

Results The workshop participants collectively identified 106 research questions organized around four system-level requirements that a high-functioning LHS must satisfy. The workshop participants also identified a new cross-disciplinary integrative science of cyber-social ecosystems that will be required to address these challenges.

Conclusions The intellectual merit and potential broad impacts of the innovations that will be driven by investments in an LHS are of great potential significance. The specific research questions that emerged from the workshop, alongside the potential for diverse communities to assemble to address them through a ‘new science of learning systems’, create an important agenda for informatics and related disciplines.

BACKGROUND AND SIGNIFICANCE

Vision of a Learning Health System

The capability to share data—and harness its potential to generate knowledge rapidly and inform decisions—can have transformative effects on complex systems that produce goods and provide services. Within specific sectors of the economy, individual organizations and collaborating groups have leveraged their data to increase productivity, gain competitive advantage, and revolutionize business models.3–5 Domains ranging from transportation to agriculture, to environmental sciences, to supply chains, to military services and intelligence have demonstrated the capacity and need to derive significant benefits from leveraging data, systems, and human interconnectedness on ever-increasing scales.4

However, attempts to employ these types of approaches to realize transformative impacts for the most challenging societal problems—including health and education—have not enjoyed similar success. While the health sector can point to examples of large clinical research networks, as well as increasing adoption of electronic health record (EHR) systems and other information technologies, this sector has not undergone the type of IT-enabled transformation visible across other industries.6

One widely-held vision for realizing the transformations previously described, at significant scale and scope in the health domain, is generally known as the Learning Health System (LHS). A series of publications from the Institute of Medicine (IOM) 8 has described the LHS and documented the need for it. The IOM defines the LHS as a vision for an integrated health system “…in which progress in science, informatics, and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience, and seamlessly refine and deliver best practices for continuous improvement in health and healthcare.”7 Though articulated in various forms, the underlying concept is straightforward: harness the power of data and analytics to learn from every patient, and feed the knowledge of “what works best” back to clinicians, public health professionals, patients, and other stakeholders to create cycles of continuous improvement.

Consistent with the characteristics of a continuously learning system as articulated by the IOM in 2012,9 the LHS can also be thought of as common infrastructure, governance, and incentive structures coupled with shared values that enable such a health system and culture. The LHS also promises to empower a new era of personalized medicine.10 Realizing the promise of personalized medicine requires a key component of what the LHS enables—“knowing what works, understanding why it works, learning for whom it works, and applying that knowledge to address patient needs…”11

The Office of the National Coordinator for Health Information Technology (ONC) set achievement of rapid learning as the pinnacle goal of its 5-year strategic plan (2011–2015).12 In 2014, ONC identified the national-scale LHS as its 10-year strategic goal and stated that, “This ‘LHS’ should also enable lower health care costs, improved population health, truly empower consumers, and drive innovation.”13

The LHS imperative

The imperative to achieve an LHS is anchored in a number of realities of the current health system...
that render its status quo unsustainable. The USA spends roughly 18% of its gross domestic product (GDP) on healthcare, and, by some projections, could almost double that share by 2040. Healthcare spending per capita by the USA greatly exceeds that of other ‘first world’ countries, while underperforming these nations on many indices of population health status. As one study notes, “While the U.S. performs well on breast and colorectal cancer survival rates, it has among the highest rates of potentially preventable deaths from asthma and amputations due to diabetes, and rates that are not better than average for in-hospital deaths from heart attack and stroke.”

Other studies suggest that as much as $750 billion annually, approximately 25% of total expenditures, is literally wasted on administrative inefficiencies, fraud, abuse, and treatments that do not work. Even with such spending, it has long been recognized that patients do not receive over 45% of recommended care and quality is improving slowly. Such urgency itself underpins a series of LHS-related IOM reports dating back to 2007.

There is a growing recognition of the US healthcare system’s inability to routinely study its own behaviour; an LHS would provide such capability, and would significantly address many of the current challenges faced by the system. For example, researchers required 4 years to recognize that a commonly prescribed drug was leading to tens of thousands of deaths. In the presence of an LHS infrastructure to support routine surveillance leveraging timely data from a population the size of the USA, this safety signal could have been detected in approximately 2 months. Researchers who developed and tested analytic methodologies for learning from EHR data, utilizing the UK’s General Practice Research Database (GPRD), highlighted the importance of learning at large scale. These researchers concluded that, “Ideally future databases should be much larger than GPRD, which includes about eight million patients. On the basis of our work to date, we estimate that 40–50 million patients are needed for the breadth of future studies we can envisage.”

The growing recognition of the importance of an LHS is seen in an increasing number of publications, amplying the calls from the IOM. For example, a 2013 editorial in the New England Journal of Medicine cites the LHS as one of three essential steps needed to reduce healthcare’s ‘GDP Footprint,' while another has challenged all academic health centers to become LHSs, so they can be drivers of needed change in health research and health care delivery. Further illustrating the emerging national imperative, the entire July 2014 issue of Health Affairs was devoted to the potential of ‘big data’ to transform healthcare and health, including an extensive discussion of a new rapid-learning agenda.

Overall, realizing the LHS on a national scale by harmonizing and synergizing multiple efforts has taken on many features of a “Big Hairy Audacious Goal,” which “changes the time frame and simultaneously creates a sense of urgency….”

Pathway and progress toward an LHS

A foundation for the LHS is emerging as the nation’s healthcare system becomes increasingly digital. This is due in part to an estimated over $30 billion federal investment to promote meaningful use of health information technology through the HITECH Act provisions of the American Recovery and Reinvestment Act of 2009. Averaging several indices, the nation’s health system is approximately 35% digital now but is expected to be 80% digital by 2019. Interoperability requirements built into HITECH will make significant but imperfect progress toward standardizing data stored in EHRs.

Other foundational elements of a national LHS include organizations that, within their own boundaries, have become LHSs. While several organizations have made significant progress toward learning status, Kaiser Permanente, Geisinger Health System, and the US Veterans Administration stand out as examples of institutions that are already harnessing the power of data to improve the health of the populations they serve. In addition, federated learning networks among independent organizations have formed to share data and harvest the benefits of learning from it, with the HMO Research Network, the Vaccine Safety Datalink, the Food and Drug Administration (FDA) Mini-Sentinel, and CancerLinQ as key examples. These developments both document the benefits to be derived from a nationally-scaled LHS and suggest that a national-scale LHS is technically and organizationally achievable. A recent paper examining four emerging data networks concludes: “these four programs [are] examples of the first stage in the development of a shared national big-data resource that leverages the investments of many agencies and organizations for the benefit of multiple networks and users.”

From these developments, it is evident that achievement of a national-scale LHS will not be the work of a single organization, stakeholder group, or governmental entity. Rather, it is anticipated that the LHS will require active participation of and cooperation among multiple and diverse stakeholders, nationwide and ultimately globally. While there is increasing national focus in the USA, the LHS is increasingly a global phenomenon. There is increasing collaboration among international and multinational initiatives including TRANSFoRm (which “aims to develop the technology that facilitates a learning healthcare system” for the European Union), with explicit recognition that key LHS enablers such as standards should be developed in ways conducive to global harmonization.

The LHS research agenda

The LHS is a consummate challenge for researchers across a range of scientific disciplines. Progress at each stage of development will require the best possible answers to an enormously wide range of questions.

The scope of these challenges was first suggested at a 2010 IOM workshop that focused on the digital infrastructure for the LHS. Participants in this workshop identified the LHS as an ultra-large scale, ultra-complex, cyber-socio-technical system, recognizing that at a national and ultimately global scale, the LHS is a massive system of systems. That same year, in a separate study addressing similar issues, a group of researchers wrote: “The U.S. urgently needs a major initiative to develop software and systems engineering foundations for a national-scale health information network (NHIN). The NHIN will be an ultra-large-scale (ULS) system. An ULS systems perspective therefore must guide these activities.”

It follows that achieving the LHS vision requires more than merely addressing difficult engineering challenges; profound and difficult socio-technical challenges will need to be addressed by bringing together a wide-range of disciplines. Moreover, the LHS is not a ‘build out’ project. Along the way, many challenges—including government policies, competition among healthcare providers, rivalries among technology vendors and developers, concerns related to balancing privacy and security against the value created by secure sharing of data—will need to be addressed. The LHS will need to be sustainable through a sound business and governance model. The complex trans-disciplinary work ahead may build upon emerging specializations of the past
decade, including “implementation and integration sciences... the theory and methods necessary to tackle complex societal issues and problems”.42

METHODS: THE WORKSHOP
In this spirit, the National Science Foundation convened a 2-day invitational workshop to identify the fundamental scientific and engineering research challenges to achieving a national-scale LHS. The workshop was planned by a 12-member committee and ultimately engaged 45 prominent researchers spanning multiple disciplines over two full days in Washington, DC on 11–12 April 2013. While fully recognizing that the LHS is ultimately a global challenge and that the findings would have potential to generalize across national boundaries, support from a US national agency directed a national focus for the workshop.

The participants were challenged to view the LHS as a ‘system after next’.43 As such, the LHS can succeed only by creating novel combinations of role, process and technology. This must occur by working back from the future, not by figuring out how to fix the various problems with a current system that fails to learn rapidly, routinely, and at scale.

The research questions, that were the focal product of the workshop, developed through two rounds of breakout group deliberations. In each round, the participants divided into four groups with different composition. In the first round, each group examined one of four use cases describing the operation of a high-functioning LHS at scale. The use cases separately addressed LHS operation in support of health care quality, of a high-functioning LHS at scale. The use cases separately addressed LHS operation in support of health care quality, population health, personal health, and biomedical research and illuminated what learning could mean—and how it could ultimately improve health—in each of these contexts. Each group identified the research challenges that must be addressed to realize a very high-functioning LHS capable of executing its assigned use case. The LHS use cases may be found at http://healthinformatics.umich.edu/lhs/nsfworkshop.

In the second round, each group focused on one of four broad system-level requirements for the high-functioning LHS:

1. An LHS trusted and valued by all stakeholders
2. An economically sustainable and governable LHS
3. An adaptable, self-improving, stable, certifiable, and responsive LHS
4. An LHS capable of engendering a virtuous cycle of health improvement

Each group identified the research challenges that must be addressed to realize a very high-functioning LHS capable of meeting the assigned requirement.

As part of the plenary session closing the workshop, each participant wrote the research challenge question stemming from the 2-day meeting that he/she felt was most important and that he/she could envision himself/herself being personally involved in addressing.

Following the workshop, the planning committee compiled, refined, and organized the research challenges into the form of questions. The questions were circulated back to all participants for review and comment, which resulted in further refinement of the questions. A modification of the four system-level requirements used for the second round of the workshop’s group deliberations formed the basis for organizing the key findings. Ultimately, 106 questions were generated and they were organized into 4 categories and 19 subcategories. In reviewing the report, the 19 subcategories themselves (Box 1) may paint the most comprehensive picture of the breadth and nature of the research challenge questions generated through the workshop methodology. The challenges and questions that follow form a broad scientific agenda for realizing a high-functioning LHS. Further, in addition to the granular level of findings of the research challenge questions themselves, there was a second level of transcendent findings, illuminating themes interwoven into a new science of learning systems anchored in the socio-technical challenges identified.

RESULTS: THE RESEARCH CHALLENGES AND QUESTIONS
We provide below an illustrative sample of the research challenge questions generated as a formal result of the workshop. This illustrative sample was selected from among the full set of questions (n=106). The representative sample below includes at least one question from all subcategories, containing a mix of high-level and specific questions, with an intent of conveying the perspectives deriving from the diverse disciplines represented. A full listing is available in the report itself (http://healthinformatics.umich.edu/lhs/nsfworkshop).

Requirement 1: an LHS trusted and valued by all stakeholders

What methods will be needed to measure confidence, trust, and trustworthiness?

Box 1 Learning Health System (LHS) research challenge questions: categories and subcategories

1. System requirement 1. An LHS trusted and valued by all stakeholders
   1.1 Defining, measuring, and tracking confidence and trust
   1.2 Building confidence and trust in the data inputs
   1.3 Building confidence and trust in the process
   1.4 Generating value while building confidence and trust in the outputs
   1.5 Building confidence and trust in the system as a whole

2. System requirement 2. An economically sustainable and governable LHS
   2.1 Private sector incentives and markets
   2.2 The role of the public sector in the LHS
   2.3 Conceptualizing value in the context of the LHS
   2.4 The LHS and the healthcare/health system as a whole

3. System requirement 3. An adaptable, self-improving, stable, certifiable, and responsive LHS
   3.1 An adaptable LHS
   3.2 A self-improving LHS (that builds trust in the system)
   3.3 A certifiable LHS
   3.4 A stable LHS (through trust and confidence)
   3.5 A responsive LHS

4. System requirement 4. An LHS capable of engendering a virtuous cycle of health improvement
   4.1 Rapidly creating knowledge that engenders learning
   4.2 Communication within the LHS: What mechanisms will enable communication of methods used and results obtained, in actionable forms, to all stakeholders with interest in the results?
   4.3 Building a smart system: How can the LHS become smart enough?
   4.4 Learning about learning, research about research
   4.5 Key questions specific to health improvement
What approaches will promote monitoring of confidence and trust at varying levels of scale, and thus enable improvement of the LHS over time?

Can the potential of a dataset to generate valid knowledge (fitness for use) be computed from the dataset itself? What metadata are required?

How can we analyze motives and incentives for security breaches and attacks on the LHS, and best structure governance and security policies and mechanisms to guard against them? What is the relationship between the real and perceived security of the LHS and stakeholders’ levels of confidence and trust in it?

What value metrics will assess the magnitude of improvement in health outcomes and cost-efficiency, as well as social and behavioral impacts, associated with LHS activities?

How can the LHS be designed, engineered, and operated as a self-defending and self-repairing system for purposes of protecting individual and institutional privacy and the integrity of data knowledge against malicious attack and accidental disclosure?

**Requirement 2: an economically sustainable and governable LHS**

What value is the LHS uniquely capable of producing, for which stakeholders, and how can this value be identified, measured, and incentivized? How can the science of networks, markets, game theory, and mechanism design inform the design and operation of the LHS?

How can predictive models and empirical studies address what ingredients, essential to standing up and sustaining the LHS, have no private rationale for funding or are unlikely to be funded privately, and therefore should be considered for catalyst stemming from public funding? How can lessons from other rapid learning systems and ultra-large scale systems in other sectors be applied to thinking about incentives and markets vis-à-vis the LHS?

How can predictive models and empirical studies address the relationship between incentive structures and data sharing and other key activities essential to the function of the LHS that will advance the public interest?

**Requirement 3: an adaptable, self-improving, stable, certifiable, and responsive LHS**

What features of the LHS, as a socio-technical ecosystem, will best position it to incorporate innovation in data sources that include real-time monitors, sensors, and devices intended to augment bodily functions and directly improve a person’s health?

How do we combine data generated in learning-from-doing and from observational data with careful experiments to be sure knowledge is scientifically solid and valid for stated purposes, but also as widely useful as possible?

What analysis must be conducted, what evidence must be gathered, and what arguments must be constructed and maintained over time, about the development, design, and operation of the system and about the environment in which it operates to enable system certification for safety, performance, and other critical system properties?

How do we make data sufficiently self-describing so that, for example, the system might be able to identify, without human intervention, data that are most relevant to addressing a question?

How can we understand and develop mechanisms to balance the tradeoff between speed (rapidity) and accuracy?

**Requirement 4: an LHS capable of engendering a virtuous cycle of health improvement**

What existing analytical and inferential methods serve the needs of the LHS, and what needs of the LHS require new methods? In particular, in the context of an LHS at scale, what methods are needed to address bias, confounding, propagation of erroneous information, spurious correlations, and other potential sources of mis-learning in the LHS?

What rigorous methods for data description and new data quality metrics will capture the semantics that enable rapid learning from (big) heterogeneous data streams? What approaches will describe fitness for use within the context of a specific purpose? For example, what are the semantics for characterizing data and identifying and describing bias?

How do we develop ways to communicate generated results, and surrounding uncertainties, to others who may wish to replicate (or build upon) the work done, as well as to the general public?

How can the LHS become smart enough to detect attempts to answer a question that is not answerable with the resources in the system?

What are the best approaches to measuring and understanding the predictive value of models resulting from big data?

What new methods are needed to determine the value of knowledge generated by the LHS and resulting actions?

To support health care quality improvement, how can the LHS develop a complex multidimensional model of a person’s future health status and communicate it to them or their trusted health-care provider to promote their health and wellbeing?

**DISCUSSION: THE LHS AND AN EMERGING SCIENCE OF CYBER-SOCIAL LEARNING SYSTEMS**

The challenges and specific research questions—organized into four areas corresponding to requirements a high-functioning LHS must meet—constitute one level of expression of the workshop’s findings. At a higher level, the findings in their totality and their multiple interactions generate a broader perspective, suggesting that rising to the challenge of the LHS may require a novel emergent science of large-scale learning systems best seen as an evolution from the science of information systems, through a science of cyber-physical systems, and ultimately to a science of cyber-physical-social ecosystems. While these concepts were explicitly discussed, the workshop did not describe this new science in detail, but rather was suggestive of it, with the LHS providing the real world, imperative, driving problem that brings this science into sharper focus. A second workshop product was therefore the suggestion of this new perspective, the applicability of which may transcend the health domain that was the original focus of this workshop.

Sciences have been developed and refined to study information systems, systems responsible for the digital representation, processing, storage, transmission, and use of information enabled by advances in computer science and engineering, as well as other fields. A next generation science of cyber-physical systems has also emerged, driven by advances in sensors, the ongoing miniaturization of digital computers, the wireless networking of edge devices to massive cloud computing systems, computer control of robotic machinery, and machine learning and artificial intelligence. After considering the challenges associated with realizing a national-scale LHS, the workshop participants came to recognize cyber-social ecosystems as a next step in this evolution.

A national-scale LHS will have to be understood and designed as such a cyber-social ecosystem: a large-scale, decentralized,
human-intensive, cyber-catalyzed and cyber-supported information processing system. 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. So, for example, trust in the digital infrastructure is necessary to induce privacy-sensitive citizens to agree to permit information flows that are critical enablers of computations essential to the beneficial operation of the system. Institutions with commercial interests in the data that they generate will have to be incentivized or otherwise motivated to transmit such data under certain conditions.

From this perspective, the LHS cyber-infrastructure must be understood as a platform that empowers multiple and diverse stakeholders to individually and collectively drive innovation across the healthcare ecosystem. By serving as a platform that enables data as a service to facilitate and incentivize data sharing and data use, the LHS will underpin a host of unforeseeable innovations in data-, knowledge-, and evidence-driven healthcare, bio-surveillance in the public interest, and health-related research and development. Just as no one involved in the creation of the Internet in the 1960s could have reliably predicted the ultimate emergence of Google, Amazon, Facebook, or Twitter, no one today can predict what the LHS will catalyze in the decades to come. Yet, just as some original visionaries saw the emergence of personal computing and an “intergalactic computer network” (that grew into the world wide web) ahead of their times, establishing a robust foundational framework for the LHS, with many elements articulated in the aforementioned IOM reports, will enable analogous types of emergent future possibilities, growth, and evolution. If it is properly designed, the LHS can be expected to have profoundly catalytic effects on future innovation for health, healthcare, and the economy.

Achieving a learning system will require discovery of methods to loosely couple the parts of this complex ecosystem in ways that enable them to align with one another over time. Just as the Internet easily survives the loss of component systems due to loose coupling, and just as it fosters the emergence of completely unforeseen functions, so an architecture enabling loose but influential coupling in the health ecosystem will allow each component of the system to participate in the evolving network while maintaining its own autonomy, pursuing its own interests, and optimizing its own performance, while also being able to rely on trusted other parts of the system doing their parts in concert.

In sum, the findings of this workshop identify a host of deeply important, difficult, and unresolved research issues at the intersection of computer science, software and systems engineering, the behavioral and social sciences, healthcare, clinical medicine, research and statistical methodologies, and public health. The authors and the workshop participants recognized that addressing the deep scientific questions related to the LHS—from which many of which will be anchored in the new envisioned science of cyber-social ecosystems—will require not only collaboration among multiple and diverse stakeholder types, but will also require research, learning, and innovation to occur at the intersection of multiple and diverse disciplines. No one discipline alone has the tools or knowledge requisite to attack this multifaceted sociotechnical challenge. It follows that neither the research community currently organized around the National Science Foundation (NSF) alone, nor around the National Institutes of Health (NIH) alone, has the requisite intellectual capabilities to empower this emerging scientific perspective comprehensively.

The LHS requires a new and significant crossing of capabilities that today are present only in these largely disconnected communities. Realizing this goal will require the NSF to continue to expand its embrace of health and healthcare as a driving domain for fundamental research, as it will require the NIH to expand its embrace of computing as a transformative power for biomedical research and healthcare innovation and delivery. The potential benefits are manifold. If the LHS is successful, there will be important lessons for how to leverage large amounts of real-world data, mechanisms for learning from such data, feedback components aimed at mobilizing lessons learned to inform decisions and actions, and cyber-social ecosystems—entailing networks of computers, machines, people, and organizations—to improve performance and bring about transformation in many other sectors outside of health. Therefore, additional mechanisms, of which this workshop was one starting point, and resources to bring together the largely disconnected research communities, will be needed to underpin an interdisciplinary, multi-stakeholder journey to realize such promise.

The specific research questions that emerged from the workshop, alongside the potential for diverse communities to assemble to address them through a “new science of learning systems”, were deeply exciting to the workshop participants.

Contributors The authors have participated to varying extents in the preparation of this manuscript, but all have met the four authorship criteria listed below: substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; drafting the work or revising it critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Data sharing statement A set of documents which reports the findings of the workshop in much greater detail, including all 106 research questions, can be accessed (http://healthinformatics.umbich.edu/LHS/nsfworkshop).

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