



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).

- 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.



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

62 Endorsements of the LHS *Core Values** (As of 6/25/2014)



*To be included on a Learning Health Community public website that will list all organizations that have endorsed the LHS *Core Values*.



July 20, 2012

Developed at the May, 2012 Learning Health System Summit

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.

Template of LHS *Core Values* Endorsement Letter
Revised: November 1, 2013

Contact: Joshua C. Rubin, Josh@JoshCRubin.com

LETTERHEAD of Organization

<date>

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

Executive Office
M.C. 22-01
100 North Academy Avenue
Danville, PA 17822
(570) 271 6168 Tel
(570) 271 6927 Fax

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

GEISINGER
HEALTH SYSTEM

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).

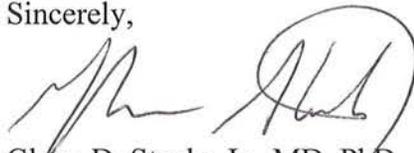
The learning health system (LHS) will support the transformation of American healthcare to which we are all committed, enabling us to learn more rapidly from the increasing amounts of digitally stored health information—to help individuals make better-informed care decisions, to improve patient care, 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](#) [1], 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](#) [2]. 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](#) [3] 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](#) [4] and [Stage 7 hospitals](#) [5] 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

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 [6].

Language:

English

Contacts:

Joyce Lofstrom [7]

Source URL: <http://press.himss.org/press-release/himss-supports-national-scale-learning-health-systems-core-values>

Links:

[1] <http://kanterhealth.org/featured/2012-summit/>

[2] <http://www.iom.edu/Reports/2012/Best-Care-at-Lower-Cost-The-Path-to-Continuously-Learning-Health-Care-in-America.aspx>

[3] <http://www.himss.org/policy/d/PolicyPrinciples2011.pdf>

[4] http://www.himss.org/davies/pastRecipients_org.asp

[5] <http://www.himssanalytics.org/emram/stage7Hospitals.aspx>

[6] <http://www.himss.org>

[7] <http://press.himss.org/node/32>

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.

##



Strength Through Collaboration

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.

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

AHIMA Endorses LHS Core Values

AHIMA HAS JOINED a list of nearly 60 prominent healthcare organizations, vendors, and associations in their endorsement of the Learning Health Community’s Core Values that will underpin the collaborative development of a national-scale Learning Health System. Also, the founding members of the Learning Health Community’s Interim Steering Committee have been slated to speak at the upcoming AHIMA Convention and Exhibit in September. Other entities who have endorsed the Learning Health System include:

- American Medical Informatics Association (AMIA)
- GE Healthcare IT
- Geisinger Health System
- Healthcare Information and Management Systems Society (HIMSS)
- Johns Hopkins Medicine
- Siemens Health Services
- University of Michigan
- WellPoint

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

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..."¹ 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."² 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."³ 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

(AHRQ) National Healthcare Quality Reports, indicates that healthcare quality improves at a rate of merely two percent per year—requiring 35 years to double.

- **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.⁴ 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 systemically 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.
- **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 de-

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.

scribed by patient advocate “e-Patient Dave” deBronkart in a 2012 speech—his first major speech “about the value of information to everyone engaged in any aspect of health or care”—if a doctor reads two journal articles every night, at the end of each year, he or she would fall over 400 years behind the flow of research articles created (a statement paraphrasing Dr. Donald Lindberg, director of the US National Library of Medicine). Yet healthcare is not doing a great job of putting such information in doctors’ hands through clinical decision support and other mechanisms other than reading when and where it is called for.

Support for LHS is Spreading

The previously cited statistics characterize the enormity of the problems that result, in large part, from a healthcare system that cannot learn routinely and at scale, and highlight the transformative potential of empowering all stakeholders in the healthcare 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.’”^{5,6} 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 pediatric LHS.

Indeed many large health systems are using their ever-increasing 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 addressed 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 stakeholders to collaboratively realize a national-scale, and ultimately global-scale, LHS. Models of large-scale, sustained, multi-stakeholder collaboration that have enabled the development of enduring 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 Summit 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 participate 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 collaboration.

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 characteristics 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 driving the Essential Standards to Enable Learning (ESTEL) launched over a year ago in the community's fertile environment. The Learning Health Community has also begun to catalyze other self-organizing initiatives 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. ●

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Joshua C. Rubin (Josh@JoshCRubin.com) is executive program officer for Learning Health System Initiatives at the University of Michigan School of Information. He currently also serves as a member of the Learning Health Community's Interim Steering Committee. Charles P. Friedman (cpfried@umich.edu) is professor of information and public health, and director of the health informatics program at the University of Michigan. He also serves as chair of the Learning Health Community's Interim Steering Committee.



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