



Weaving Together A HEALTHCARE Improvement Tapestry

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

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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:

- ñ 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.
- ñ 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:

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

- ñ 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.
- ñ 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:

- ñ **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.
- ñ **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.

- ñ **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.
- ñ **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.
- ñ **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.
- ñ **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.

- ñ **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.
- ñ **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.
- ñ **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. ○

Notes

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