Achieving a Functioning Learning Health System by 2024:

The Challenges and Benefits of a Successful Journey

Holt Anderson, FHIMSS
Principal, Learning Health Strategies
Chair, Governance & Policy Framework Initiative of the Learning Health Community

W. Ed Hammond, PhD, FACMI, FAIMBE, FIMIA, FHL7
Director, Duke Center for Health Informatics
Chair Emeritus of HL7

NCHICA 21st Annual Conference & Exhibition
Pinehurst Resort
Pinehurst, North Carolina
September 15, 2015
Session Objectives

• Describe the goal to achieve an operational LHS by 2024 that ONC has established as a core objective in its 10-year plan.

• Describe the steps the research community is taking to identify, assemble, analyze and make data available to support an LHS.

• Discuss the work of clinical, legal, and operational experts who have been charged to develop a policy and governance framework that will engender accountability and trust in the LHS.
The Learning Health Community (LHC)

- The LHC developed as one outcome of the 2012 “Learning Health Summit” sponsored by the Joseph H. Kanter Family Foundation
- A self-organizing, multi-stakeholder coalition of the willing
- Currently there are 86 “Endorsers” of the LHS Core Values
- 1st LHS Summit Planning Committee is now the LHC’s Coordinating Committee
- CDISC, as a 501(c)(3), serves as the fiscal agent for the LHC
- The Learning Health Community acts to catalyze, lead, and participate in initiatives to realize the Learning Health System:

![Diagram of Learning Health Community structure]

- ESTEL Essential Standards to Enable Learning
- Governance & Policy Framework Initiative
The Core Values Underlying a National-Scale, Person-Centered, Continuous-Learning Health System (LHS)

1. Person-Focused
2. Privacy
3. Inclusiveness
4. Transparency
5. Accessibility
6. Adaptability
7. Governance
8. Cooperative and Participatory Leadership
9. Scientific Integrity
10. Value
86 Endorsements of the LHS Core Values*
(As of 8/12/2015)

* Included on www.LearningHealth.org
One Vision of an Operational LHS:

1. In the future, a Learning Health System will be an almost invisible tool used during a clinical encounter between an individual and a health professional (in-person or virtual).

2. The tool will provide knowledge gleaned from the analysis of hundreds or thousands of similar individuals with the same symptoms, test results, diagnoses, and outcomes from their treatments.

3. The best results from this analysis will be provided to inform the clinical decision that is made for the subject individual.

4. After the results from this treatment are known, that will be fed back into the population data so future encounters will benefit from that knowledge.
Benefits of an Operational LHS:

- **For the Individual**: The very best treatments informed from the information gleaned from other encounters, treatments and outcomes.

- **For the Health Professional**: Better information to assist decision making and more quality time with the individuals they are diagnosing and treating. *

- **For Researchers**: Enhanced access to larger and richer data sets for analysis.

- **For Pharmaceutical and Device Providers**: Identification of conditions that provide more precise targets for their product development efforts.
* The LHS will be embraced by the Health Professional:

• **If** the system is properly designed and implemented.

• If the LHS is an **almost invisible tool** that informs the health professional without undue searching, sorting, and decision making.

• Perhaps there will be other components in the LHS “system” including a **clinical decision support system (CDS)** that does all of the data manipulation in the background and prepares the top choices for decision making.

• …with the **number of choices** being shown predetermined by the health professional (e.g., “show me the best 3 or 5 choices for treatment of the individual in front of me”).
Developing a Governance and Policy Framework for an Operational Learning Health System:
The Trust Foundation for Data Sharing
4. **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.
The point of departure for the governance initiative will be several working assumptions about the structure of a national-scale LHS.

-- The national-scale LHS will be a **structured, collaborative, multi-stakeholder effort**: a system comprised of sub-systems bound together by a common policy and governance framework agreed to by any organization electing to participate and willing to be legally bound by the multi-party agreement that all parties must execute before participating.

-- The sub-systems comprising the LHS will be heterogeneous, open to all stakeholders in the nation’s health sector, including but not restricted to: provider organizations, payer organizations, patient/consumer groups, research organizations, technology companies, professional associations, and government agencies including public health that can comply with the agreement that binds all participants to a common set of expectations and responsibilities.

-- These heterogeneous entities will have different reasons for being part of the LHS. They will contribute in differing ways to the LHS and will derive differing benefits.

-- In order to be stable and sustainable, the national LHS will require some form of governance, likely reflected in a compact or multi-party agreement that all sub-systems will formally endorse. Agreement to comply with the current version of the ESTEL standards will be a key component of this compact along with other standards, policies and procedures that will be a part of the structure. A draft of the agreement is expected to be the primary deliverable of the governance initiative.

-- The governance initiative will view the LHS as an ultra-large scale system and will be one that enables growth, evolution, self-repair, and change.

-- While these sub-systems themselves may consist of sub-sub-systems, the governance of the LHS will extend only to its own direct sub-systems but may need to take into account any chain-of-trust implications dependent on the data sharing work flow.

-- The governance of a national LHS is expected to be a **public-private partnership**, not residing within the federal government.
Task Force Meetings
ONC Recognition & Leadership for an LHS

Connecting Health and Care for the Nation
A Shared Nationwide Interoperability Roadmap

DRAFT Version 1.0
Governance & Policy Framework Task Force

I. Reviewed and analyzed the ONC Roadmap from a governance and policy perspective.

II. Developed comments and recommendations for ONC.

III. Developed consensus on most important recommendations and next action steps.
From the Task Force Recommendations:

• The Task Force recognizes that our experience with the EHR Incentive Program and the Medicare Shared Savings Program has been largely EHR-centric. As a more unified approach begins to emerge that combines precision medicine and small-big-long data, and as public and population health emerges in communities, the Task Force encourages ONC to insist that the Learning Health System governance structure take a more expansive view of interoperability and incentivize broader thinking around these health and payment models.

• The Task Force requests that ONC include administrative data along with the other forms of electronic health information specified in the Roadmap draft to ensure that the learning cycles are fully informed with all of the available information for individuals.
Task Force Next Steps

• Identify and reach out to organizations engaged in the aggregation, analysis, and sharing of health information
• Collect examples of existing multi-party agreements that enable information sharing
• Invite participation by SMEs and organizations who might wish to be participate in this activity
• Maintain neutral perspective and non-advocacy for a particular sector
• Analyze those agreements to identify practices that might be useful in a strategic, potential governance structure
• Publish analysis and any recommendations that will support the LHS
Anticipated Challenges & Principles with Reciprocal Benefits Needed to Establish a Trust Framework

• Competition
• Control of Data
• Intellectual Property & Exploitation of Knowledge
• Privacy & Potential Sanctions for Breaches

• Economic Incentives & ROI
• Stimulation of Innovation

• Technology
• Work Flows
Contact:

Holt Anderson, FHIMSS
Principal, Learning Health Strategies
Chair, Governance & Policy Framework Initiative
Learning Health Community
lhs@nchica.org

http://www.learninghealth.org
Another Perspective on the Learning Health System

W. Ed Hammond. Ph.D., FACMI, FAIMBE, FIMIA, FHL7
Director, Duke Center for Health Informatics. DTMI
Director, Applied Informatics Research, DHTS
Director of Academic Affairs, MMCi Program
Professor, Department of Community and Family Medicine
Professor Emeritus, Department of Biomedical Engineering
Adjunct Professor, Fuqua School of Business
Research Professor, School of Nursing
Duke University
Chair Emeritus, HL7

www.dchi.duke.edu
Questions we might ask

• What does Learning Health mean?
• What is a Learning Health System?
• What purpose does it serve?
• What are its benefits?
• What are examples?
• What other initiatives are related?
• Why has it become so important?
In Lewis Carroll's *Through the Looking-Glass*, Humpty Dumpty discusses **semantics** and **pragmatics** with Alice.

"I don't know what you mean by 'glory,'" Alice said.

Humpty Dumpty smiled contemptuously. "Of course you don't—till I tell you. I meant 'there's a nice knock-down argument for you!'"

"But 'glory' doesn't mean 'a nice knock-down argument'," Alice objected.

"When I use a word," Humpty Dumpty said, in rather a scornful tone, "it means just what I choose it to mean—neither more nor less."

"The question is," said Alice, "whether you can make words mean so many different things."

"The question is," said Humpty Dumpty, "which is to be master—that's all."

Alice was too much puzzled to say anything, so after a minute Humpty Dumpty began again. "They've a temper, some of them—particularly verbs, they're the proudest—adjectives you can do anything with, but not verbs—however, I can manage the whole lot! Impenetrability! That's what I say!"
What is a Learning Healthcare System?

Evidence Based Medicine + Practice Based Evidence

Learning Healthcare System
What is a learning health care system?

• The IOM’s vision:
  • Research happens closer to clinical practice than in traditional university settings.
  • Scientists, clinicians, and administrators work together.
  • Studies occur in everyday practice settings.
  • Electronic medical records are linked and mined for research.
  • Recognition that clinical and health system data exist for the public good.

• Evidence informs practice and practice informs evidence.
Why we need Learning Health

• Clinicians document what they were taught in medical school.
• Clinicians document only want they want to see at the next visit.
• We think the purpose of the EHR is to document care rather than a basis for continuing care, evaluation, patient safety, and a contribution to new knowledge.
• We still support the concept of secondary uses rather than continuous use.
• We keep our knowledge in our head.
Intersection of the EHR with the Learning Health System

- Improved health & health care through research, innovation & dissemination

- Women’s Health
- Health Systems Organization & Finance
- Preventive Care & Health Promotion
- Mental Health and Behavioral Medicine

- Biostatistics
- Cancer Prevention & Control
- Chronic Illness Care
- Immunization
Learning Health is part of …

• Population Health
• Predictive Analytics
• Precision Medicine
• Big Data
• Artificial Intelligence and Decision Support
• Consumer Involvement
• 21st Century Cures
• Sharing
Learning ... what?

• We need to establish the syllabus for learning health.

• How do we learn what do we need to learn?
  • By comparing our outcomes with other institutions
  • By recognizing what does not work as well as it could
  • By recognizing what needs to be changed
  • By recognizing what is better

• When we find a problem and fix it, we need to automate that process so the solution is applied automatically.
Table N

- Modeled after Table 1 from clinicaltrials.gov
- Provides a high level summary of an institution’s EHR
- Documents significant performance factors
  - Controlled diabetics
  - Hospital acquired infection
  - Readmission
  - Inappropriate use of ER
- Learn who is best and why, then duplicate
Technology

• Learning Health means keeping up with new technology
  • Recognize change is continuous
  • Design to accommodate change
  • Define what is required and find appropriate technology to achieve.
  • Culture innovation (disruptive) and vision
  • Never except “We don’t do it that way.”
  • Believe anything is possible.
  • Don’t be bound by how we do it today.
Health Indicators

Burning Platform: Overwhelming Complexity

Sets of Facts per Decision

- Proteomics and other effector molecules
- Functional Genetics: Gene expression profiles
- Structural Genetics: e.g. SNPs, haplotypes

Decisions by Clinical Phenotype

Human Cognitive Capacity


Recalibrating Informatic's "True North" | William W. Stead | May 27, 2010 | 2010 AMIA NOW!
Artificial Intelligence

• Knowledge exceeds the ability of humans to use available facts to make decisions

• Computers are becoming able to learn from data and knowledge that is available on the internet and other sources. Computers are becoming self-aware. Create new knowledge.

• Increase the use of decision support algorithms.

• Reevaluate the complete status of a patient with every new set of data entered into the EHR.
Registries

• Tool for Learning Health
• Permits management of disease and patients
• Permits evaluation and comparison
• Highlights performance

• Types of registries
  • Patients
  • Chronic Disease
  • Rare disease
  • Implantable devices
  • Communities
Learning Health requires new methods for visualizing big data

Source: Novel Visualization of Large Health Related Data Sets. Grant W81XWH-13-1-0061
Embracing Learning Health

• Be willing to change the way you do things.
• Rethink boundaries.
• Remove silos.
• Share ideas, methods, credit
• Create new working relationships
• Translational medicine is what it’s all about.
• Quality and trust is mandatory.
Contact:

W. Ed Hammond. Ph.D., FACMI, FAIMBE, FIMIA, FHL7
Director, Duke Center for Health Informatics. DTMI
Director, Applied Informatics Research, DHTS
Director of Academic Affairs, MMCi Program
Professor, Department of Community and Family Medicine
Professor Emeritus, Department of Biomedical Engineering
Adjunct Professor, Fuqua School of Business
Research Professor, School of Nursing
Duke University
Chair Emeritus, HL7

www.dchi.duke.edu