Developing a Policy & Governance Framework for an Operational Learning Health System

Discussion with the NCHICA Informatics & Analytics Roundtable

April 7, 2015
What is a Learning Health System?

• IOM Report Released March 30, 2007

• The most pressing needs for change identified in The Learning Healthcare System are those related to:
  • Adaptation to the pace of change
  • Stronger synchrony of efforts
  • New clinical research paradigm
  • Clinical decision support systems
  • Tools for database linkage, mining, and use
  • Notion of clinical data as a public good
  • Incentives aligned for practice-based evidence
  • Public engagement
  • Trusted scientific broker
  • Leadership

LHS Concept

“The LHS aims to harness the power of ever increasing amounts of health data captured in digital forms in order to engender ongoing cycles of knowledge generation and curation, tailored feedback, and transformative change…”

http://www.learninghealth.org/
Core Values Underlying a National-Scale, Person-Centered Continuous Learning Health System (LHS)

Developed at the May, 2012 Learning Health System Summit
73 Endorsements of the LHS Core Values*
(As of 3/23/2015)

*To be included on the www.LearningHealth.org website.
The Learning Health Community: A Grassroots, Self-Organizing, Multi-Stakeholder Movement
Core Values Underlying a National-Scale Person-Centered Continuous Learning Health System (LHS)

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.
Policy & Governance Initiative
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.
Initial Meetings Oct. 26-27, 2014
NCHICA, Research Triangle Park, NC
Roadmap for U.S. HealthGrid for Biomedicine
March 2006
ISO Collaborators

TATRC

2013

ESTEL

June 2014

ONE LHS
FOR 2024

9/11 ESTEL
in Austin

IOM

LHS Summit
MAY 2012

DATA SUPPLIERS/USERS

* Federal/State Govt., ACOs, public health
* Researchers - clinical, basic science, etc.
* Schools
* Registries - disease, societies, databases, international, immunization
* Care providers - clinical, home care, nursing, outpatient, community health
* Companies - EHR, pharma, mobile/telecom, payers, certification, etc.
* INDIVIDUALS, communities
* Non health sectors - energy, environment, security, defense

Policy & Governance Framework Task Force

Families, consumers, socials (neighbors, friends)
DATA SUPPLIERS/USERS

- Federal/State Government, PEOs
- Public Health - State, Local, Regional, Federal, Global, International
- Researchers - Clinical, Basic Science, etc.
- Schools
- Employers
- Care Providers - Clinical, Home Care, Nursing, PHCs, Community Health
- Companies - EHR, Phrama, mobile/telecommunications, IT services, technology, vendors, developers
- Individual ALS, Communities
- Other sectors - energy, environment, security, defense, professional associations, medical specialty societies

Oct 27, 2012 - Google Social Media
CFO - Larry Gainer
**LHS Timeline – DRAFT FOR DISCUSSION**

1. **Roadmap for US HealthGrid for Biomedicine**
   - March 2006

2. **LHS Summit**
   - 2007

3. **IOM**

4. **LHS Summit**
   - 2012

5. **ESTEL**

6. **ONC Strategic Plan LHS for 2024**
   - June 2014

7. **ESTEL in Austin**
   - September 2014

8. **Policy & Governance Task Force**
   - October 2014

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**Goal**

- **Multi-Party Agreement/Governance Structure in Place**
- **Pilot LHS**
- **Functioning LHS “In Production”**
- **LHS V x.0**
- **LHS V y.0**

*Dates Unknown*

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*U Michigan; DOD TATRC; 150 Collaborators*
Connecting Health and Care for the Nation
A Shared Nationwide Interoperability Roadmap

DRAFT Version 1.0
Governance & Policy Framework Task Force

- Reviewed and analyzed the ONC Roadmap from a governance and policy perspective
- Developed comments and recommendations to include in comments submitted to ONC on April 3rd
- Representatives of the Task Force met on April 6th to:
  - Review submission to ONC
  - Develop consensus on most important recommendations
  - Agree on next steps
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.
Task Force Ranking of Most Important Recommendations

• The appropriate definition of Governance sparked the most discussion among members of the Task Force, and the Task Force encourages ONC to take a stronger and more prominent role in encouraging the realization of a Learning Health System governance process that provides a role for all stakeholders. The Health Information Technology industry should be encouraged to support the maximum degree of openness compatible with healthy competition and market innovation. ONC should work with all stakeholders involved in, or that would be impacted by, the governance process to develop a set of rules of the road that ensure a realistic timeline to interoperability but one that is informed by the urgency of the outcome.

• To support the desired outcome, we encourage ONC to develop a strategy of continuous evaluation and process improvement relative to the governance framework.
The Task Force recommends that great care be taken to ensure that the vision of the national Learning Health System be person-focused and that emphasis is placed on individuals, whether patients or not, their families, interested parties and caregivers as central, and that traditional players such as providers, hospitals, payers, etc. are there to serve individuals and not the other way around.

The Task Force further recommends that, whenever the context allows, broader terms such as “health” and “wellness” be used rather than more restrictive terms such as “medical care,” “nursing care,” etc.
The Task Force proposes that ONC select examples of governance efforts involving multiple stakeholders from across the U. S. to inform the development of an effective governance and policy framework to support an interoperable, nationwide and potentially international governance structure. ONC should provide a forum for these pilot governance efforts to convene, explore, and develop a more comprehensive and consistent governance framework that minimizes inconsistencies and simplifies interoperability from a policy and governance perspective.
Task Force Ranking of Most Important Recommendations

• The Task Force encourages ONC to consider how individuals, patients and care professionals can be included in the Learning Health System governance process.

  Tied with:

• The Task Force proposes that ONC develop a governance structure and associated policies that encourage all participants in the Learning Health System to envision and to realize the development of a national digital health infrastructure that is person-centric. This infrastructure should incorporate and promote a “connect anytime and anywhere” approach to currently existing data in healthcare and other pertinent environments.
The Task Force recommends that ONC explicitly indicate that lay caregivers are included in the term ‘caregivers.’ We further recommend that transition of care be explicitly included in the continuum of care.

The Task Force further recommends that ONC consider how the necessary cultural shift can be more fully described and how progress in such a cultural shift can be measured.
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
Challenges & Principles Needed to Establish Trust Framework

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

• Economic Incentives & ROI
• Stimulation of Innovation

• Technology
• Work Flows
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