Achieving a Functioning Learning Health System by 2024: The Challenges and Benefits of a Successful Journey

Charles P. Friedman, PhD – Chair, Dept. of Learning Health Sciences, Univ. of Michigan Medical School
Holt Anderson, FHIMSS - Learning Health Community
Angel Hoffman, RN, MSN – Principal, Advanced Partners in Health Care Compliance

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Disclosure: Conflicts of Interest

Charles P. Friedman, PhD
Chair, Dept. of Learning Health Sciences, Univ. of Michigan Medical School

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

Angel Hoffman, RN, MSN
Principal, Advanced Partners in Health Care Compliance

Except for a disclosure by Dr. Friedman, the speakers have no real or apparent conflicts of interest to report.
Learning Objectives

• Describe the aspirations for achieving an operational LHS by 2024 that ONC has established as a core objective in their 10-year interoperability roadmap.

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

• Discuss the work of a team of clinical, legal, and operational experts that have been charged to develop a policy and governance framework that will engender accountability and trust in the LHS.

• Raise awareness of participants to better prepare for your organization’s participation in a LHS environment.
The Learning Health System
&
The Learning Health Community

Charles P. Friedman, PhD
Josiah Macy, Jr. Professor of Medical Education
Chair, Department of Learning Health Sciences
Professor of Information and Public Health
University of Michigan
June 23, 2015
Disclosure

I am the chair of the Interim Steering Committee of the Learning Health Community, a grassroots not-for-profit organization.
The Learning Health System

Health systems--at any level of scale--become learning systems when they can, continuously and routinely, study and improve themselves.

Perspective: Jan 3, 2013
“Code Red and Blue — Safely Limiting Health Care’s GDP Footprint”
Arnold Milstein, M.D., M.P.H.

...U.S. health care needs to adopt new work methods, outlined in the Institute of Medicine’s vision for a learning health system...
Vision of a National Learning Health System

Bound by Trust  Decentralized  Reciprocal

All-Inclusive

Governance  Engagement  Data Aggregation  Analysis  Dissemination

Insurers  Pharma  Patient Groups  Tech Industry  Universities  Government/Public Health  Research Institutes  Healthcare Delivery Networks
A Health System That Can Learn

• Every consenting person’s characteristics and experience are available to learn from
• Best practice knowledge is immediately available to support decisions
• Improvement is continuous through ongoing study
• This happens routinely, economically and almost invisibly
• All of this is part of the culture
How To Learn: “Virtuous Cycles” of Study and Change, Leading to Improvement

A Problem of Interest

- Assemble Experience Data
- Analyze Data
- Interpret Results
- Take Action
- Tailored Messages to Decision-Makers

Decision to Study
The LHS Requires Infrastructure: A Common Platform Supports Multiple Simultaneous Learning Cycles
A Learning Health System Infrastructure *Routinely* Enables:

- Pursuit of Best and Safer Care at Lower Cost
- Enhanced Public Health
- Consumer Empowerment
- Accelerated Research
Learning Systems Can Exist at Any Level of Scale

• The scale of the system = the scope of the platform
• Local, state, national, global
A Decentralized, All-Inclusive Ultra-Large Scale System *Can’t* be Built from a Blueprint!

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Elements of a National Learning System are Assembling

1. Words: calls and reports
2. Care documented in digital form
3. Single organization “Learning Islands”
4. Multi-organization data federations and networks
5. Grant programs
6. An emerging research community
7. The Learning Health Community: A grassroots coalition
LHS “Summit” May 2012

• Consensus conference to envision LHS as set of shared beliefs

• ~ 70 organizations represented at the National Press Club

• Resulted in 10 consensus Core Values

• 80 organizations have formally endorsed the Core Values
LHS Core Values

www.learninghealth.org/about-the-community

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

*Additions will be included on the www.LearningHealth.org website.
The Learning Health Community

• Grew out of the 2012 Summit
• A self-organizing, multi-stakeholder coalition of the willing
• Community = 80 “endorsers” of the Core Values plus ~1,500 individuals
• CDISC now hosts the Learning Health Community
• Works through initiatives: two underway, several more to come

learninghealth.org
Learning Health Community
Initiatives

Launched February, 2013

Launched October, 2014
Essential Standards to Enable Learning (ESTEL) Charter

To define a parsimonious/essential/minimum core set of standards that could enable a standards-based yet flexible and scalable LHS in accordance with the following goals:

a) Ease the burden for any clinician to participate in a research study or other learning activity;

b) Increase the capacity for learning from data;

c) Obtain knowledge and results in an actionable form to contribute to building the LHS;

d) Ensure that the data obtained can be readily aggregated and/or compared; and

e) Ensure that the data uphold scientific integrity.
Thanks & Write to Me

cpfried@umich.edu
Developing a Governance and Policy Framework for an Operational Learning Health System

Holt Anderson, FHIMSS
Chair, Governance & Policy Framework Initiative
Learning Health Community
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
2. Privacy
3. Inclusiveness
4. Transparency
5. Accessibility
6. Adaptability
7. Governance
8. Cooperative and Participatory Leadership
9. Scientific Integrity
10. Value
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 workflow.

-- 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

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 19 pages of comments and recommendations submitted to ONC on April 3rd

III. Representatives of the Task Force met on April 6th to:
   a. Review submission to ONC
   b. Develop consensus on most important recommendations
   c. Agree on next steps
Selected 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.
Selected Task Force 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.
Selected Task Force Recommendations

• 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.
Selected Task Force Recommendations

• 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.
Selected Task Force 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 *nationwide 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.
Selected Task Force Recommendations

• 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
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

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• Economic Incentives & ROI
• Stimulation of Innovation

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• Technology
• Work Flows
Contact:

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

http://www.learninghealth.org
Angel Hoffman

Phone: 412-559-6703

Email: Angel@APHCcompliance.com

www. APHCcompliance.com
Providers, Insurers and Others as a Part of the Learning Health Community (LHC)

A look at what this group will be worried about…

A lot of the issues parallel the challenges we face with HIEs
Review of the Core Values…
as a Participant of the LHC

Person focused –
- Not company focused (self interests)
- Not revenue focused
- No political agenda
- Focus on wellness and preventative care
Privacy focused –
- How will the person’s PHI be protected?
- Who will have access to the data?
- Who owns the data?
- Where will it come from?
- How will it be secured?
- Who is responsible for updates and notifications of changes?
Inclusiveness–

- This means open to everyone; not limited to a few select individuals
- How will the activity and the participants be governed? Will there be rules?
- Each partner needs to have equal weight and the large or wealthier company should not have more say or dictate to the others for personal gain.
Challenges

Competition
- In this arena all bets are off!
- There is no room for unhealthy competition and no need to engage in game playing
- Trust is key here among participants
Challenges

Control of Data

- Governance is an important issue
- There needs to be criteria regarding how PHI will be protected and secured
- Breach Notification and how that applies
Transparency—

- Something which everyone can understand
- No hidden criteria
- Information about the operations is available
- Not a secret society
Accessibility –

- Who can access the data? Individual and organizations who have permission
- By what means?
- In what format?
- Protecting the information regardless from where it comes
Challenges

Intellectual Property & Exploitation of Knowledge

► We want transparency, but…
► We must be respectful to the other participants/stakeholders
► We cannot get into legal battles over I.P. or let internal or trade secrets get out (could have information that could be considered insider trading if released)
Governance –

- Legal responsibilities (e.g. I.P.)
- Need to develop a framework
- Development of policies
- Accountability and trust
Challenges

Economic Incentives & ROI –

Governance is necessary to support:
- A sustainable operation
- To set required standards
- To build and maintain trust on the part of all stakeholders
- To stimulate ongoing innovation.
Challenges

Privacy & Potential Sanctions for Breaches

- Breach Notification application
- Creating the governing body to address this
- Unauthorized access to data (PHI)
- Notification to individuals
- Accounting of Disclosures
Cooperative and Participatory Leadership

► Working together for the common good… HEALTH and WELLNESS!!!

► Leadership is not bullying others, because you are the bigger organization

► Can it be done? Can we “play nice” with others?

► Collaborative and multi-stakeholder effort
Scientific Integrity –

- Accuracy of the data
- Is the data reliable?
- Can we depend on it, in as far as, clinicians can make decisions based on the data?
- How can we be sure that it is updated with new information in a “timely” fashion?
Challenges

Stimulation of Innovation
- Advances in Medicine
- Research based changes
- Advances in Technology
- Keeping up with demographics
- Tracking and identifying trends (e.g. working with the CDC)
Challenges

Technology

- Development of new imaging equipment
- Development of new approaches to surgery
- Development of new medications
- Will everyone be able to implement it and afford the new technology?
Value –

- Quality
- Impact to revenue
- Decrease in overall costs
- Public satisfaction
- Clinician satisfaction
Challenges

Work Flows

- Putting it all together
- Establishing and maintaining processes
- Do we imagine “opt in” and “opt out” process for both individuals as well as participating organizations?
- Developing the overall strategy is key to moving forward
Impact to Individuals, Families and their Health Care Providers

- Education of the public
- Instill **confidence** that individuals **can** manage their own health
- Education of clinicians
- Relax some control on the clinician side
FOLLOW-UP DISCUSSION