Session # 26
Achieving a Functioning Learning Health System by 2024 – The Challenges and Benefits of a Successful Journey

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DISCLAIMER: The views and opinions expressed in this presentation are those of the author and do not necessarily represent official policy or position of HIMSS.
Disclosure: Conflicts of Interest

- Catherine Costa, RN, MTM - ONC
- Rebecca Kush, PhD - CDISC
- Holt Anderson - Learning Health Community
- Ricky Bloomfield, MD – Duke Health

The speakers have no real or apparent conflicts of interest to report.
Learning Objectives

• Participants will understand the aspirations for achieving an operational LHS by 2024 that ONC has established as a core objective in their 10-year plan.

• Participants will learn about the steps the research community is taking to identify, assemble, analyze and make data available to support a LHS.

• Participants will learn about 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.
ONC Comments

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Innovator-in-Residence
U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
The Learning Health Community and its ESTEL Initiative

Rebecca D. Kush, PhD
President & CEO – CDISC
Steering Committee – Learning Health Community
The Learning Health Community

- Grew out of the 2012 “Learning Health Summit” sponsored by the Joseph H. Kanter Family Foundation
- A self-organizing, multi-stakeholder coalition of the willing
- Now 70+ “endorsers” of the Core Values plus ~1,500 others expressing interest
- “Summit” Planning Committee became the Community’s Coordinating Committee
- CDISC now hosts the Learning Health Community as a 501(c)(3)
- Catalyzing, leading, and participating in initiatives to realize a Learning Health System:
  - Standards (ESTEL)  
    (initiated February 2013)
  - Governance & Policy  
    (initiated 27 October 2014)
  - Technology
**Learning Health Community**

- Infrastructure can enable necessary virtuous cycle of study, learning and improvement

- This requires assembly of data, analysis, and feedback

**CORE VALUES ENDORSED**

- Person-focused
- Privacy
- Inclusiveness
- Transparency
- Accessibility
- Governance
- Cooperative and Participatory Leadership
- Scientific Integrity
- Value
73 Endorsements of the LHS Core Values*  
(As of 3/23/2015)

*To be included on the [www.LearningHealth.org](http://www.LearningHealth.org) website.
The Learning Health Community: A Grassroots, Self-Organizing, Multi-Stakeholder Movement
Essential Standards to Enable Learning (ESTEL) Charter

Purpose and Scope:

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.
Research findings to inform healthcare decisions

Information from healthcare (private, aggregated) to enable research

Currently Inefficient
~17-year cycle

Healthcare
• Quality healthcare
• Informed decisions
• Personalized medicine
• Patient safety and privacy
• Public health
• Improved therapies
• Efficiencies/reduced costs

Research
• Discovery of new therapies
• Understanding diseases
• Testing/comparing therapies (CER)
• Assessing efficacy
• Monitoring safety
• Understanding responses (genomics, biomarkers)
• Public health/quality evaluations
• Post-marketing surveillance

Research Healthcare
Data Exchange Among Physicians – NOT ‘Interoperable’

Exchange within organization

- 38.9% Any exchange with other providers
- 34.6% Any exchange: Inside the organization
- 27.9% Providers inside office/group
- 28.2% Affiliated hospitals

Exchange outside organization

- 13.8% Any exchange: Outside the organization
- 12.7% Providers outside office/group
- 4.8% Unaffiliated hospitals
Current Environment for Clinical Research – Biopharmaceutical Development

- Time and cost of developing a drug increased dramatically
- Biopharmaceutical companies focused on profits in developing products
- Research studies more complex for numerous reasons
- Many clinicians do one study and no more
- Only a small percentage of eligible patients participate in research
- Data re-entered from the EHR or Medical Record into Research (e)Case Report Forms
- EHR use increasing, but NOT used *prospectively* for research
- Research and Healthcare still seem ‘separate worlds’
eSource = data entered electronically first, i.e. EHRs, eDiaries....
Value of Using Standards Even Greater Now!

2014 Business Case

Current Landscape 2014

- Study Complexity
- # Datapoints
- Data Management
- Time/Resources
- Cost of Research

2007 CDISC Business Case

Quantifying the Value of CDISC Standards Implementation (Cycle Time Savings)

- Analysis/Reporting
- Study Conduct
- Study Start-Up

Note: Figures are benchmarks based on aggregate data; study-specific cycle times and cost metrics will vary.

Study Conduct does not include subject participation time.
Synergistic Standards Currently Available for EHR-enabled Research

Healthcare Delivery

- eSource Documents EHR
- HL7 CCDA

Medical Research

- iHE Integration Profiles (e.g. RFD)
- ODM
- CDISC SHARE
- eCRFs

eArchive at Clinical Site - CDISC
ASTER (AE Reporting from EHRs)
30 Ambulatory care physicians at Harvard and Brigham and Women’s with Pfizer, CDISC, CRIX
Nov 08 – Jun 09, > 200 Reports Sent to FDA

Physician Reporting:
*91% of participating physicians had submitted no ADE reports in the prior year
*During the study, participants reported an average of approximately 5 reports in a 3 month time period
*All participants reported at least 1 AD
*Process: Time to report decreased from ~35 min to < 1 min

Source: Michael Ibara, Pfizer
What does all of this have to do with the Learning Health System, Learning Health Community and Essential Standards to Enable Research (ESTEL)?
A Learning Health System Should Support…

- BIG data for data mining, signal detection, analytics
- High quality Research data for and Public Health case studies for Data Science
- Outcomes research and Epidemiology
- Other Learning Cycles
Learning Health Community
ESTEL Learning Cycle Framework

1. Observe; Record
2. Analyze
3. Assemble Results
4. Inform; Act
5. Observe; Record

Raw Data -> Analytic Data
Aggregate; Tabulate

Health Experience

Inference; Interpretation

Guidance
The Learning Health Cycle Framework can serve as a tool leading to specifications of Essential Standards to Enable Learning. It can also become a standard in its own right. The Learning Health Cycle Framework:

a) defines what it means to be a player in this ecosystem;
b) provides a way to identify when a set of activities qualify as a Learning Health Cycle;
c) requires the articulation of key entities and key relationships among the entities;
d) requires efferent and afferent arms of the cycle with the proposed ‘cycle points’ shown in the final cycle depicted above;
e) creates a benchmark for identifying consensus-based standards to work in specific implementations for the domain of interest at each step of the loop;
f) will require that data accumulating at one step in a learning loop be semantically annotated to a sufficient degree to fulfill requirements for the next stage in the loop;
g) adheres to the Learning Health Community Core Values;
h) meets the ESTEL goals; and,
i) is scalable.
Criteria for ESTEL Standards

- A good standard for a Learning Health Cycle meets the following criteria:
  - meets the purpose for intended use;
  - is not redundant to another standard;
  - developed through a robust, consensus-based standards development process, preferably by a global standards development organization;
  - mature and broadly used/adopted;
  - is open and freely available (not proprietary) and is protected by an IP policy to remain that way;
  - is maintained, with support, education and certification where applicable.
ESTEL Framework Document: Structure and Standards

Example of Framework Applied to Clinical Research

<table>
<thead>
<tr>
<th>Component</th>
<th>Description of Activities</th>
<th>Available Standards</th>
<th>Support for US Value Streams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data &amp; Knowledge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data</td>
<td>Data are aggregated into a database, from which tables, figures, and analysis are generated.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analysis</td>
<td>Data are interpreted and provided in the form of tables, figures, and analysis that are shown in the report. Standards exist in the form of quality standards and quality manual.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information Management</td>
<td>Data are stored in a database and can be retrieved. Data are then analyzed and presented as tables, figures, and analysis. Standards exist in the form of quality standards and quality manual.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

According to the Institute of Medicine of the National Academies (US), “A Learning Health System (LHS) is one in which progress in science, informatics, and care culture align to generate new knowledge as an ongoing, natural product of the care experience, and seamlessly refine and deliver best practices for continuous improvement in health and health care.”

ESTEL Framework Document Draft: 7 March 2015
www.learninghealth.org

Please Comment on the ESTEL Framework Document

Provide Your Example of a Learning Cycle

rkush@cdisc.org
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 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 may consist of 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.
Recent Meeting April 6-7, 2014
NCHICA, Research Triangle Park, NC

Pictured Below
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 to submit 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
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.

- Additional Recommendation

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 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.
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
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
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http://www.learninghealth.org
LHS: A Physician’s Perspective

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Healthcare is Hard

Newton’s Laws of Motion

"Every object persists in its state of rest or uniform motion in a straight line unless it is compelled to change that state by forces impressed on it."

"Force is equal to the change in momentum (mV) per change in time. For a constant mass, force equals mass times acceleration."

\[ F = m \cdot a \]

"For every action, there is an equal and opposite re-action."
Healthcare is Hard

Photo credit: NASA
Why is it so hard to fix people?
What does this mean for patients and providers?

**Generate**
- We need higher quality data (and more of it)

**Integrate**
- We need to make it easier to move that data between patients and providers

**Evaluate**
- We need better tools to automate analysis of that data
Integrate SMART® + FHIR
Evaluate

EHR Vendors

hadoop

mongoDB
The Future

**Collect**

**Goal 1:** Expand adoption of Health IT

**Share**

**Goal 2:** Advance secure and interoperable health information

**Use**

**Goal 3:** Strengthen health care delivery

**Goal 4:** Advance the health and well-being of individuals and communities

**Goal 5:** Advance research scientific knowledge and innovation
Questions?