Envisioning the Necessary Policy & Governance Framework to Support an Operational Learning Health System (LHS)

An Overview of an Emerging LHS and Components Leading to an Operational Status by 2024

DRIVERS

A Supportive Payment & Regulatory Environment

POLICY & TECHNICAL COMPONENTS

STANDARDS & FUNCTIONS
- Secure, Standard Services
- Consistent, Secure Transport Technique(s)
- Directories & Resource Location
- Consistent Data Semantics
- Consistent Data Formats
- Accurate Individual Data Matching
- Ubiquitous Secure Network Infrastructure
- Verifiable Identity & Authentication
- Consistent Representation of Authorization
- Shared Decision-Making Rules of Engagement & Accountability
- Industry-wide Testing & Certification Infrastructure
- Consistent Understanding & Technical Representation of Permission

OUTCOMES

A learning health system enabled by nationwide interoperability, that supports all stakeholders, especially individuals and providers.

- Individuals
- Public Health
- Human Services
- Research
- Payers
- Providers
- Technology Developers
Emerging VISION of an Operational LHS Environment

**Stakeholders who INDIRECTLY Interact with Individuals**
- Government Regulators
- Accrediting Entities
- Public Health Entities
- Registries
- Researchers
- Software & Services
- Pharma
- Medical Device Suppliers
- Wellness Device Suppliers
- HIEs

**Stakeholders who DIRECTLY Interact with Individuals**
- Providers & Public Health
- Payers (Government & Private)
- Labs
- Pharmacies
- Employers
- Patient Advocates
- Support Groups

**Direct Interactions**
- Acute Care
- Post Acute Care
- Long-Term Care

**In-person at:**
- Hospital
- Office
- Clinic
- Retail Store
- Home

**Remote by:**
- Phone
- Computer

**COMPREHENSIVE DATA:**
- Symptoms
- Diagnosis
- Genetics
- Treatments
- Outcomes
- Side Effects
- Environmental Factors

**AUTHORIZED SHARING**

**LEARNING HEALTH SYSTEM (LHS)**

**Virtuous cycle of continuous study, learning, and improvement**

**Data Analysis Interpretation Feedback Change**

**IMPORTANT AND RELATED INITIATIVES INCLUDE:**
- pcori
- NCIN
- MVI
- wmg
- UMC
- Home Health Monitoring
- COMPENDIUM OF NATIONAL GUIDELINES
- EUA
- AHRQ
- RESEARCHERS
- SOFTWARE & SERVICES
- ACCREDITING ENTITIES
- REGISTRIES
- MEDICAL DEVICE SUPPLIERS
- WELLNESS DEVICE SUPPLIERS
- GOVERNMENT REGULATORS
- PHARMACIES
- EMPLOYERS
- PATIENT ADVOCATES
- SUPPORT GROUPS
- GOVERNMENT
- REGULATORS
- PUBLIC HEALTH ENTITIES
- PHARMA
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**Remote by:**
- Home Health Monitoring
LHS = “Network of networks that connects islands of expertise”

Current Initiatives Leading to an LHS Capability Include:
INFLUENCING FACTORS & CHALLENGES INCLUDE:

• Building Trust with Individuals and Among Competing Organizations
• Fostering Leadership Among Health and Healthcare Professionals
• Developing Positive Value Propositions for Direct and Indirect Stakeholders
• Incorporating Transition from FFS to Value-based/Outcomes-based Care
• Achieving Compatible Data Standards and Technology Interoperability
• Adoption of Legal and Policy Standards to Enable Data Exchange on a Broad Scale (even Internationally)
• Communicating Steps to Achieving Operational LHS
• Developing Channel of Communication with Media Organizations
• Managing Expectations of the Availability of LHS Capabilities
• Solving Issues Directly Impacting Individuals Including:
  • Ability to Pay
  • Availability and Access to Care
  • Health and Technology Literacy
## GAPS to be Overcome to Achieve the LHS Vision

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>TODAY - 2016</th>
<th>VISION - 2024 or Before</th>
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<tbody>
<tr>
<td>Access to Healthcare</td>
<td>Limited</td>
<td>Universal</td>
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<tr>
<td>Diagnosis / Treatment / Outcome</td>
<td>Based on Provider’s Experience &amp; Personal Network</td>
<td>Based on Global Information about Similar Individuals</td>
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<tr>
<td>Mind and Body</td>
<td>Mental and Physical Health are Separate</td>
<td>Individual as a Single Whole</td>
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<tr>
<td>Health Ownership</td>
<td>Some Individuals Take Ownership, but Most Do Not</td>
<td>Completely on the Individual</td>
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<tr>
<td>Health Records</td>
<td>Some Paper, Some Electronic</td>
<td>All Electronic</td>
</tr>
<tr>
<td>Interoperability</td>
<td>Limited</td>
<td>Universal</td>
</tr>
<tr>
<td>Records Accessibility</td>
<td>Limited</td>
<td>As Needed</td>
</tr>
<tr>
<td>Data Security</td>
<td>Questionable</td>
<td>Secure</td>
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<tr>
<td>Collaboration</td>
<td>Seemingly Forced</td>
<td>Genuine</td>
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<tr>
<td>Legal and Policy Barriers</td>
<td>Each Country and Each State have Different Laws</td>
<td>Similar laws across borders</td>
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<tr>
<td>Intellectual Property</td>
<td>Fears of Repercussion</td>
<td>Innovative and Incentivizing</td>
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# LHS Governance & Policy Framework Initiative Workgroups

<table>
<thead>
<tr>
<th>WG 1: Coordination with ESTEL activities</th>
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<tbody>
<tr>
<td>WG 2: Develop a value proposition for LHS stakeholders</td>
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<tr>
<td>WG 3, 4: Develop principles and examples to inform governance and policy structures, standards, information and monitoring to support an LHS</td>
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<td>WG 5, 6, 8: Develop communications and messaging including collaborative approaches with ONC and other LHS-related organizations.</td>
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<tr>
<td>WG 7, 9: Identify/obtain grant funding for meetings and related activities (long-term &amp; short term as well as video).</td>
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WG3 combined with WG4; WG5 and WG8 combined with WG6; WG7 combined with WG9
Current Methodology Utilized by Policy & Governance Framework Initiative

• Analyze and map motivations, incentives, value equations, etc. for major participants/stakeholders
• Develop understanding of relationships between and among stakeholders
• Envision changes required to reach an operational LHS including perquisites and dependencies for each action
• Create a Critical Path Timeline as a visual guide to the role of each stakeholder and their position(s) on the timeline
• Communicate with ESTEL and other members of the LHC
107 Endorsements of the LHS Core Values*
(As of 10/14/2016)

*To be included on the www.LearningHealth.org website.
What will be your contribution???