



Submitted via: [www.healthit.gov/interoperability](http://www.healthit.gov/interoperability)

April 3, 2015

Dr. Karen B. DeSalvo, MD, MPH, MSc  
National Coordinator for Health Information Technology  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

RE: Comments on ***Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap – Draft Version 1.0***

Dear Dr. DeSalvo:

We are appreciative of the work of ONC in preparing this very important document that continues the process of enabling a Learning Health System for the Nation, and we are pleased to provide comments that focus on the rules of engagement and governance.

The Learning Health Community established the Governance and Policy Framework Initiative in 2014 as a complement to the Essential Standards to Enable Learning Initiative (ESTEL) that was formed following the LHS Summit in Washington, DC in May 2012 sponsored by the Joseph H. Kanter Family Foundation. An important outcome of the Summit was a set of Core Values for a Learning Health System that currently is endorsed by 72 leading organizations (see Appendix A & B).

Over sixty-five individuals representing a broad and diverse set of skills and perspectives expressed an interest in convening to developing a consensus-based framework for the trust foundation to enable an operational Learning Health System with a set of assumptions provided by the Steering Committee of the Learning Health Community (see Appendix C) and divided themselves into 9 Workgroups with voluntary leadership (see Appendix D).

ONC's release of the Interoperability Roadmap has provided an opportunity for the Governance and Policy Framework Initiative members to form a special Task Force to comment specifically on those areas in the Roadmap that intersect with the charter of this group. What follows represents largely a consensus set of opinions and recommendations but where additional discussion will be required to reach consensus, it is noted.

We hope this is useful in moving to the next steps in achieving the Learning Health System and we certainly would be pleased to respond to any questions you might have regarding this submission.

Handwritten signature of Charles P. Friedman in black ink.

---

Charles P. Friedman, PhD  
Chair, Interim Steering Committee  
Learning Health Community

Handwritten signature of Holt Anderson in black ink.

---

Holt Anderson, FHIMSS  
Chair, Governance & Policy  
Framework Initiative



## THE GOVERNANCE AND POLICY FRAMEWORK INITIATIVE OF THE LEARNING HEALTH COMMUNITY:

### COMMENTS ON THE RULES OF ENGAGEMENT AND GOVERNANCE: A CRITICAL PART OF THE SHARED NATIONWIDE INTEROPERABILITY ROADMAP

#### I. Overarching Comments to the Roadmap

##### A. ONC-Specific Questions:

1. *Are the actions proposed in the draft Interoperability Roadmap the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?*

##### Comment:

The Task Force believes the Roadmap represents a good start toward the realization of an operational Learning Health System but there is a need for a clearer vision of how an operational LHS would manifest itself during and encounter between an individual and a health professional who is informed by the information produced by the LHS. A well thought out governance and policy framework will provide the foundation necessary to achieve this essential goal.

2. *What, if any, gaps need to be addressed?*

The Task Force appreciates that tackling electronic health information used for administrative purposes is a daunting task. However, by not including administrative data (i.e. claims and ADT) in the Roadmap, ONC is unnecessarily delaying the integration of these data with clinical, social, and environmental information and potentially creating multiple independent data sets and uncoordinated efforts in the future.

##### 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.

3. *Is the timing of specific actions appropriate?*

##### Recommendation:

The Task Force would suggest that ONC produce a clear vision of an operational Learning Health System at a point in the future and reverse engineer all of the components/tasks required including their prerequisites and dependencies with underlying assumptions about who and when each of the tasks could be completed and the entity responsible for each of those tasks. Known as a "Critical Path Method of Scheduling," this would make the process visible and transparent and engender a sense of responsibility and accountability on the part of each of the crucial entities.

4. *Are the right actors/stakeholders associated with critical actions?*

**Comment:**

The Task Force acknowledges the importance of the “stakeholder perspectives” provided in Figure 5 in the section “Who is this Roadmap For.” We have extended these stakeholder perspectives with additional value propositions and barriers for each. These are provided as Table 1 to this document. Please note that in developing these extended stakeholder perspectives, the Task Force has taken a person-centered perspective focusing on health and what is important to the individual, their families, and the degree of wellness and their care.

B. **General Comments:**

ONC's vision for a Learning Health System presents a picture of ubiquitous health information in which individuals have greater engagement, caregivers have better information and tighter coordination, and evidence from research and prior encounters becomes central to the delivery of care. This vision will expand the role of both Covered Entities under HIPAA, on the one hand, and entities that may be neither a Covered Entity nor a Business Associate of Covered Entities, on the other. Enabling such an expansion of exchange, use, and disclosure, as well as the involved entities, will require extensive re-evaluation of current and perceived legal barriers to and enablers of exchange, as well as expansion of protections to non-covered entities. In addition, the ability of any entity to condition the delivery of services on waiver of any protections will need to be addressed. For example, many Personal Health Records operate on the theory that a patient authorizes a Covered Entity to disclose health data to the Personal Health Record.

**Recommendation:**

The Task Force recommends that ONC work with its federal partners and the private sector to close this loophole in HIPAA protections.

II. **Comments Specific to the Rules of Engagement and Governance**

A. **ONC-Specific Questions**

*The draft interoperability roadmap includes a call to action for health IT stakeholders to come together to establish a coordinated governance process for nationwide interoperability. ONC would like to recognize and support this process once it is established. How can ONC best recognize and support the industry-led governance effort?*

The use of the term ‘health IT stakeholders’ seems unduly restrictive and implies that the IT community is the sole group actors to bring forth the governance and policy solutions necessary to enable the LHS. In its 10-year interoperability concept paper, ONC used the phrase “connecting health and care for the nation.” This is a more inclusive phrase and seems more appropriate to and effort as comprehensive as the Learning Health System.

**Recommendation:**

The Task Force proposes that ONC use the more inclusive term “health and care stakeholders,” which would, of course include health IT stakeholders as a subset.

In the section entitled "Background and Current State", ONC acknowledges that one component of governance is the conferring of authority. ONC's question presupposes that a group of Health IT stakeholders will be able to aggregate, create a governance process and obtain authority. Without further action to confer authority (or require adherence) to any one governance mechanism, multiple governance mechanisms are likely to develop.

**Recommendation:**

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.

**B. Comments specific to the LHS Requirement**

*Shared governance of policy and standards that enable interoperability: Nationwide interoperability across the diverse health IT ecosystem will require stakeholders to make collective decisions between competing policies, strategies, standards in a manner that does not limit competition. Maintaining interoperability once established will also require ongoing coordination and collaborative decision-making about change.*

Please refer to the comments regarding governance in Section IIA above. The second recommendation provides a mechanism for collective decision making. Establishing interoperability is undoubtedly difficult, but until a base governance approach is developed, long term scoping for coordination and collaborative decision-making will be difficult.

**C. Comments about the Federal Health IT Strategic Plan Objectives Supported**

*Improve health care quality, access and experience through safe, timely, effective, efficient, equitable and person-centered care*

*Increase the adoption and effective use of health IT products, systems and services*

*Identify, prioritize and advance technical standards to support secure and interoperable health information*

*Accelerate the development and commercialization of innovative technologies and solutions*

*Increase user and market confidence in the safety and safe use of health IT products, systems and services*

**Comment:**

The Task Force supports these objectives.



## D. Comments Regarding Background and Current State

### 1. **Governmental Governance to Enable Interoperability**

ONC's early approach with regard to AHIC, NHIN/NwHIN/eHealth Exchange, the DURSA, and NeHC were a great success in sponsoring a laboratory for health information exchange. While ONC did not move forward with a more formal governmental-led approach to eHealth Exchange, the build up to the question framed the governance, policy and technical issues for the nation. We would suggest the same approach, here.

### 2. **Non-Governmental Governance**

**(Roadmap, page 29)**

*Additionally, some vendors and organizations have chosen not to participate in any of these organizations due to uncertainty about the industry and ONC's direction, or due to the costs associated with participation. The result is a complex web of electronic health information sharing arrangements that create some degree of interoperability within specific geographic, organizational and vendor boundaries, but fail to produce seamless nationwide interoperability to support a learning health system.*

The EHR Incentive Program as well as the Medicare Shared Savings Program both required participating organizations to quickly develop capabilities in response to their respective requirements. Development of new technologies by an organization is often tailored around existing organizational-specific business practices.

#### **Recommendation:**

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. We believe this recommendation is consistent with our recommendation in II A. on the preceding page.

## E. Comments about Moving Forward and Milestones

### 1. *Governing Principles*

**(Roadmap, page 28)**

*The need for governance arises anytime a group of people or organizations come together to accomplish an end. In general, "governance is the process by which authority is conferred on rulers, by which they make the rules and by which those rules are enforced and modified."*

#### **Recommendation:**

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

**(Roadmap, page 31)**

*The private sector has a key role to play in coalescing behind a common coordinated governance process that will establish or refine the criteria that support interoperable health IT.*

*Governance should address three main subject matter areas: policy, operations and technical standards. There needs to be a single set of basic rules of the road to support interoperability nationwide and address consumer protection.*

**(Roadmap, page 37)**

*The industry response to the RFI indicated a general desire for ONC to refrain from formal governance activity and to allow nascent and emerging governance efforts in industry to take shape. As health information exchange was in its infancy, but growing at a fast pace, commenters were concerned that regulatory action would stifle innovation and improvements in health information exchange. In response to the industry's comments, ONC indicated in September 2012 that it would not move forward at that time with regulation around governance.*

**Recommendation:**

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.



## ii. Policy

**Critical Policy Issue 1:** Availability of data and decisions about the data:

All health data must be universally accessible, regardless of what technology environment is used for storage, or what individual, family, community or organization collected it. Only patients can decide whether or not their data is shared and with whom.

**Critical Policy Issue 2:** Not only must the data “in principle” be sharable, but it must be practically and easily accessible by health search engines within the constraints set forth by the governance and policy framework agreed to by those participants.

The appropriate analogy is web pages on the internet. Any web page, or data in HTML format, can be posted to the internet. The location of the data is registered with a Universal Resource Locator (URL) number. Any computer can search all the web pages of the world. However, each web page can set privacy settings to control who can see what.

### **Access to Personal Information (Roadmap, page 31)**

Individuals should be able to initiate data sharing and exchange (e.g. consumer mediated exchange) and be supported in the use of current and emerging mHealth tools across a mobile ecosystem of care providers and entities across diverse geographies.

The policies described are helpful. However, the current situation could be described as institution-centric or organization-centric and is often described as ‘consisting of silos’. What is needed is the development of a digital health infrastructure that is person-centric.

#### **Recommendation:**

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.

### **Individual choice (Roadmap, page 32)**

#### **Third sub-bullet regarding clear and simple choices.**

The Task Force offers the following extension: Choice should be controlled by the “person at the center.” It should be dynamic over time allowing revised choices about what kind of data can be shared, and with whom, and should be based on current health needs. It should support dynamic and portable consent that is “consumer mediated” and needs to be recognized as the industry standard.

### **Transparency (Roadmap, page 32)**

New technologies are in development that can support a monthly consumer report (like a credit report) that shows who has accessed, shared, consumed or reused your health data.

#### **Recommendation:**

The Task Force recommends that ONC encourage data holders and entities facilitating electronic exchange of health information to develop comprehensive and understandable methods to deliver to a patient a record of access, use and disclosure of personal health information.



### **Security (Roadmap, page 33)**

The Task Force concurs with the Roadmap's recommendation that Governance Principles address three main areas: policy, operations and technical standards, with a single set of base rules that support interoperability nation-wide and address consumer protection.

### **Security (Roadmap, page 33)**

#### **Recommendation:**

The Task Force recommends that ONC consider the growing need for interoperability and consumer protection for new and novel forms of rich contextual health data that is generated by or about individuals (including environmental, geographical, social, behavioral, imaging, genomic, wearable devices and sensor data and more).

The Task Force recognizes the growing importance of mobile devices. We also recognize that at present there are significant patient safety issues related to the interoperability of personal and medical mobile devices (e.g. where data may not be easily or accurately shared electronically), the importance of this issue will undoubtedly escalate as patients increasingly bring their self-monitoring devices and sensors into care settings. These devices and sensors will provide important new sources of data in learning health cycles for a variety of HIT and Learning Health System stakeholders.

#### **Recommendation:**

The Task Force encourages ONC to think broadly about HIT products as including both medical devices, used in clinical settings, and the emerging class of mobile health devices and sensors, that will become ubiquitous and be used by individuals anywhere and at any time. These devices will become a key component of the Learning Health System well before the end of the 10-year Roadmap timeline.

### **Individual Access and Correction (Roadmap, Page 33)**

The Task Force feels that it is important that ONC encourage the development of market solutions for consumer mediated access and for easy and convenient means of corrections to health data.

While the Task Force agrees that barriers to flow of information should not be built, configurable barriers (such as patient preferences, or use limitations based on policy) should be an inherent part of a Learning Health System. For example, a requestor obtains data under a patient authorization waiver from an institutional review board. The waiver and scope of the waiver must follow that data so it may be properly used only within the scope of the waiver.

The concept of competition based on the availability of health data is in keeping with the prohibition on the sale of personal health information. However, ONC's vision of a Learning Health System, will make personal health information ubiquitous with greater consumer engagement and with consumer options to route, use, and request health advice from many actors in the health care market besides their physician. For example, consumers may be able to independently and directly request treatment options from a provider of such "best practices" advice to health care providers. Such actors in the market (who are not necessarily Covered Entities under HIPAA), will have to abide by the same restrictions on use and sale and, especially, prohibitions against conditioning the giving of advice on waiver of these protections.

ONC's assertion regarding "Respect Policies of Other Exchange Partners" appears to be a call to level the policy field for all organizations exchanging data. While that certainly frees the flow of data, various businesses will have legitimate reasons for restricting exchange, for example, future use, as with the institutional review board example mentioned above.

#### **Comment:**

The Task Force supports ONC's position on Individual Choice. The challenge will be to present clear and understandable reasons why a certain restriction cannot be accommodated.

#### **Recommendation:**

The Task Force recommends that ONC undertake, or underwrite, an effort to categorize and catalog a standard taxonomy for refusal to accept a person-requested restriction on use or disclosure of personal health information, so individuals nationwide would have a unified understanding of these reasons.

#### **Comment:**

While the Task Force supports the idea of individual's need to request correction of personal health information, a balance must be struck between correction and annotation and the amount of additional patient-entered data (with varying degrees of reliability) a user of personal health information must review.

### iii. Operations

**Comment:**

The Task Force supports ONC's approach to Operations.

### iv. Standards

ONC should explore the possibility of using a particular “standard” (like html) that can retrieve data through permission that anyone can use, anywhere anytime regardless of where the data sits it can be accessible and useable.

Standard Development Organizations (SDOs) do not appear to be integrated throughout the Roadmap. SDO's should collaborate with transparency on progress towards standards development, maturity, adoption and harmonization.

All stakeholders need to participate in the development of appropriate standards and should not be allowed to opt out of standards activities.

**Recommendation:**

The Task Force recommends that ONC endorse a standards development process that requires all Learning Health System stakeholders to participate and that encourages the development of standards that are harmonized and aligned to support interoperability.

**Recommendation:**

The Task Force encourages ONC to think broadly about HIT products, to include medical devices used in clinical settings, and the emergence of mobile health devices/sensors which may be used in both clinical settings, and ubiquitous to the individual in their mobile lifestyle (anywhere). While there are significant safety issues related to the interoperability of medical devices today (e.g. those where data is not easily shared electronically), this issue likely will escalate as individuals submit their self-monitoring devices/sensors into care settings. These devices/sensors will be key new sources of data in learning health cycles for a variety of HIT and LHS stakeholders



F. **Comments Regarding Table 1: Critical Actions For a Coordinated Governance Framework and Process for Nationwide Health Information Interoperability**

The Task Force supports the actions identified in each of the three timeframes for Establishment of a Coordinated Governance and recommends these modifications to address noted gaps.

**Category A1. Establishment of Coordinated Governance**

Roadmap years 2015-2017:

**A1.1** The Task Force believes effective care coordination, during transitions of care, is a critical time where interoperability of health data is needed, from an individual, family, provider and payer perspective. Patient safety can be compromised. Transitions are a time where significant learning health cycles occur and are necessary feedback to assure patient safety and especially involve the person at the center in detecting errors.

**Recommendation:**

The Task Force recommends that ONC expand the focus of common rules, as a priority, from not just interoperability of a common clinical data set for the purpose of “treatment”, but also add a **second** focus on “**safe transitions of care**”.

**A1.3.** The Call to Action: The Task Force endorses the stakeholder groups identified in this roadmap, and has added some additional examples, categorization of roles, value proposition and barriers (Table 1). The public and private sector stakeholders who are forming the single governance process should be involved in identifying business practices for the prioritized Use Cases (Roadmap, Appendix H) for each of the three timeframes, assuring that all stakeholders, and their respective value propositions/barriers, are represented. A process for identifying ‘bad actors’ could focus on those who are not adhering to common business practices supporting the priority use cases and develop measures for holding those entities accountable for their actions. The Use Cases would be enhanced by cross walking these by stakeholder group, and making explicit definitions of the “learning cycle” and feedback to the ‘person at the center’, e.g. individuals and families, and other stakeholders in the Learning Health System.

**Recommendations:**

A1.6-7 The Task Force encourages the development of metrics specific to improving health and lowering cost added in the three year period 2018-2020.

A1.8-9 The Task Force would like to see new metrics developed in this final three year period, 2012-24, that move beyond interoperability of HIT, to salient measures specific to learning cycles among diverse stakeholders and learning health system achievement.



## Category A2. Policies and Operations

### Comments:

The Task Force supports the Actions identified in each of the 3 timeframes for Policy and Operations, and recommends these modifications to address noted gaps.

A2.2 The Task Force concurs with defining a policy framework for the exchange of person-generated health data and conducting pilots during the 2015-2017 period. We recommend expanding the scope of the framework, and the pilot, to include bi-directional exchange of person-generated health data into the EMR, and also bi-directional exchange of information between hospitals and public health agencies.

A2.3. The Task Force expects rapid growth of expanded data sets, including ONC's description of short, big, and long data, and data sets that are important to each stakeholder group. We believe that the expanded data sets considered in 2018-2020 should include the rich contextual data about individuals (including environmental, geographical, social, behavioral, imaging, genomic, wearable device, sensors and more).

A2.7 The Task Force applauds the focus on interoperability of clinical data to support research and big data analysis nationwide. We value the Roadmap's recognition of the need for "small, big and long data" analysis and expect that by this third time period, there is capacity for the longitudinal health data for all individuals in the nation.

A2. GAP (new Action for the 2021-2014 Period) The Task Force recommends that ONC and stakeholders participating in a coordinated governance process should define criteria and metrics for progress in the Learning Health System that show how interoperability and learning cycles are leading to breakthroughs for individuals, families, communities and populations. It is important that these criteria and ways of measuring progress be well articulated for the 2021-2014 goals.

## Category A3. Standards

### Comment:

The Learning Health Community Steering Committee supports the Actions identified in each of the 3 timeframes for Standards, and recommends encourages more explicit efforts in the middle time period (2018-2020) to evaluate the role of improved adoption of standards to improving health and lowering cost.



#### IV. Comments Regarding Interaction between Rules of Engagement and Governance and Other Building Blocks

##### **Some general observations:**

The Learning Health Community expresses its commitment to a Learning Health System with the adoption of ten core values. The first, because the most importance, is that the Learning Health System should be **person-focused**. This is taken to mean that the conceptual center of the Learning Health System is the individual, whether a patient or not, and their families, interested parties and caregivers. Hence, individuals in all these roles are as fully participatory as their needs, wants, health status and other individual, social and cultural beliefs allow. Further, the individual in all these roles becomes the center of decision making taking an active role in all health and healthcare decisions, rather than being the passive receptacle of decision making by others.

Because of this emphasis on the Learning Health System as person-focused, the Task Force is sensitive to the use of traditional terms such as 'medical' as inclusive of all healthcare related workers. This tends to take the person out of, and place other actors at, the center of focus.

##### **Recommendation:**

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", "wellness" be used rather than more restrictive terms such as 'medical care,' 'nursing care,' etc.

#### V. Supportive Business, Clinical, Cultural and Regulatory Environments

LHS Requirement

B. A supportive business and regulatory environment that encourages interoperability.

*Policy and funding levers that create the business imperative for interoperability are pivotal for helping to ensure that individuals, caregivers and providers can send, receive, find and use a common clinical data set across the care continuum in the near term. Policy levers related to other learning health system stakeholders such as public health, social and human services and research communities must also be addressed. Additionally, a cultural shift at both the individual and provider levels is necessary to empower individuals to participate in their health and care.*

##### **Recommendation:**

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.

## VI. Other Observations

### Roadmap Introduction (Page 5, Foot Note 2)

*The scope of the Advisory is on clinical health information exchange, and does not reference standards related to HIPAA transactions. The priority learning health functions are the business and technical requirements for a Learning Health System that are in the Roadmap introduction.*

The Learning Health Community currently has two initiatives directed to the realization of a national, and eventually global, Learning Health System. One is the Governance and Policy Framework Initiative, which has been the main source of the comments and recommendations provided to ONC by the Task Force. The other is the Essential Standards to Enable Learning (ESTEL), which operates under the aegis of the Clinical Data Interchange Standards Consortium (CDISC). ESTEL has introduced the concept of a “learning cycle” as a means of decomposing the enormously complex Learning Health System into units that are “stepwise implementable.”

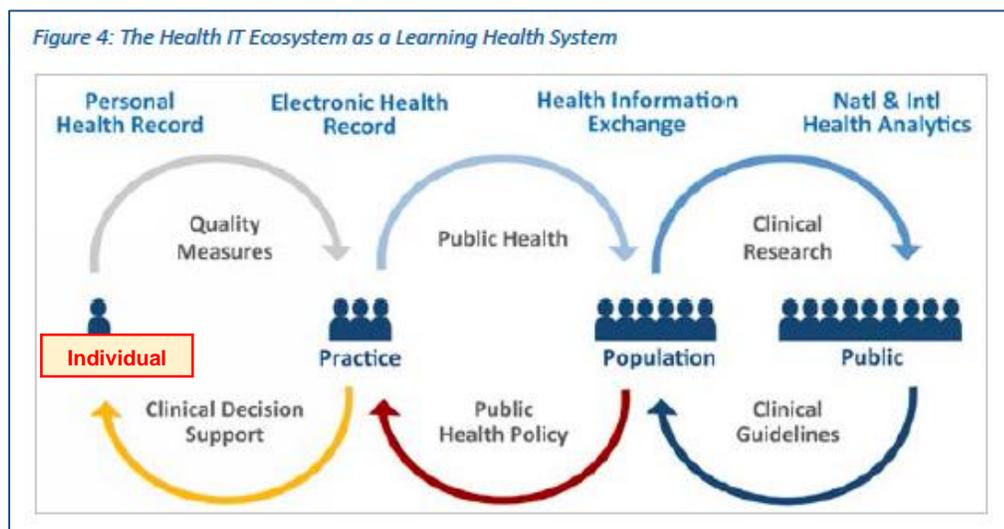
#### **Recommendation:**

The Task Force recommends that the term ‘learning health functions’ be replaced by the term ‘learning health cycles’ as units of the Learning Health System that are, in the words of the ESTEL initiative, “finite, determinate and automatable.” See “ESTEL Structure and Standards: A Framework for the Learning Health Community”, March 2015. (Appendix E).

### Roadmap Introduction (Page 19, Figure 4)

#### **Recommendation:**

Update this diagram with ‘person/individual at the center’ and include loops from the ‘person at the center’ to the stakeholders above





## APPENDIX A

# Core Values for a Learning Health System <sup>1</sup>

The design and operation of the national-scale LHS derive from its core values:

- 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.

---

<sup>1</sup> <http://www.learninghealth.org/corevalues/>



## APPENDIX B

### Endorsers of the LHS Core Values as of March 20, 2015

- 2311, LLC
- Advanced Health Institute
- Alliance for Nursing Informatics (ANI)
- Altarum Institute
- American Academy of Pediatrics (AAP)
- American College of Physicians
- American Health Information Management Association (AHIMA)
- American Medical Informatics Association (AMIA)
- American Nurses Association
- American Society of Clinical Oncology (ASCO)
- AZZLY
- Biovista
- Booz Allen Hamilton
- Boston Children's Hospital Informatics Program
- Clinical Data Interchange Standards Consortium (CDISC)
- Critical Path Institute
- Dana-Farber Cancer Institute
- Department of Primary Care and Public Health at Imperial College London
- Diogenec Group LLP
- e-Patient Dave
- Epic
- Galileo Analytics
- GE Healthcare IT
- Geisinger Health System
- Genetic Alliance
- GlaxoSmithKline
- Global Patient Identifiers, Inc.
- Harvard Pilgrim Health Care Institute
- Health Record Banking Alliance (HRBA)
- Healthcare Information and Management Systems Society (HIMSS)
- HealthCore/WellPoint
- HL7 International
- Indiana University Health
- Inland Northwest Health Services (INHS)
- Intermountain Healthcare
- Johns Hopkins Medicine
- Joseph H. Kanter Family Foundation
- Lambda Solutions, Inc.
- Lewin and Associates LLC
- MedDATA Foundation
- Medical Advocacy Mural Project
- Memorial Sloan-Kettering Cancer Center
- Minnesota Department of Health and Minnesota e-Health Initiative
- Mosaica Partners
- National Association for Trusted Exchange (NATE)
- National eHealth Collaborative (NeHC)
- North Carolina Healthcare Information and Communications Alliance (NCHICA)
- NorthShore University HealthSystem
- Oncology Nursing Society (ONS)
- Open Health Tools (OHT)
- Open mHealth
- Our Health Data Cooperative (OHDC)
- OZ Systems
- PatientsLikeMe
- Rhode Island Quality Institute
- RightCare Solutions
- Sanofi
- SAS Institute Inc.
- Scalable Collaborative Infrastructure for a Learning Health System (SCILHS)
- SecureHealthHub, LLC
- Siemens Health Services
- Texas e-Health Alliance
- The CDI Group
- The Center for Learning Health at the Duke Clinical Research Institute
- Thinkwise Health
- ThotWave Technologies
- University of Manchester
- University of Michigan
- University of Pittsburgh (School of Dental Medicine, Center for Dental Informatics)
- University of San Francisco Program in Health Informatics and School of Nursing and Health Professions (SONHP)
- Ursus Technologies (SDVOSB)
- vitaTrackr, Inc.



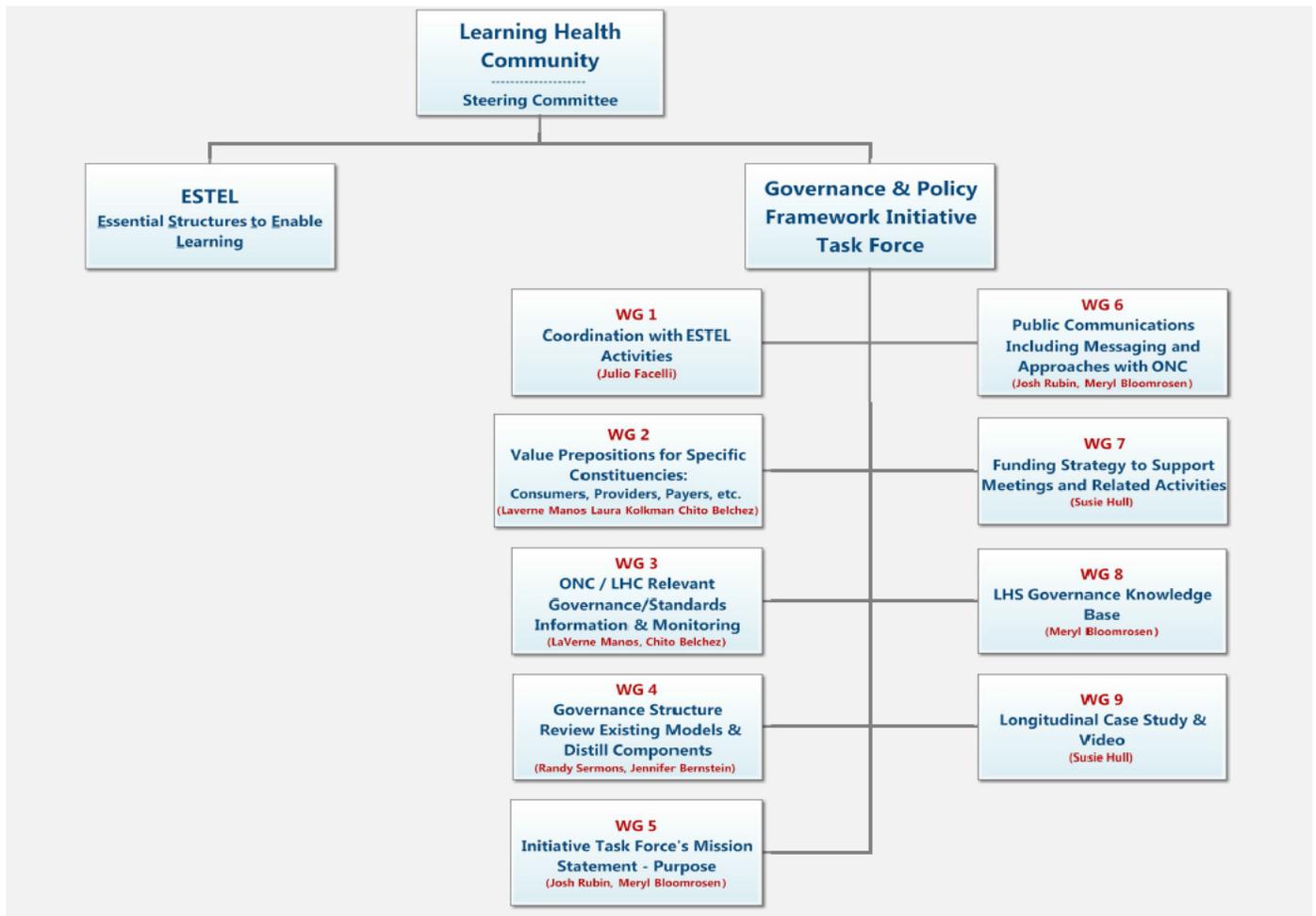
## APPENDIX C

### **Set of Assumptions Provided to the Governance & Policy Framework Initiative as Guidance by the Steering Committee of the Learning Health Community**

- 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.

## APPENDIX D

### Organization of the Learning Health Community including the Governance & Policy Framework Initiative Work Groups



## APPENDIX E



### *ESTEL Structure and Standards: A Framework for the Learning Health Community*

*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 by-product of the care experience, and seamlessly refine and deliver best practices for continuous improvement in health and health care.”*

Such a system can only be realized through coordinated collaborative efforts of a multitude of organizations and leaders who place global health improvements above individual self-interests. A Learning Health Summit in 2012 served as the launch for such an opportunity: The Learning Health Community. The mission of the Learning Health Community is to galvanize a grassroots movement in which multiple and diverse stakeholders work together to transform healthcare and health by collaboratively realizing the LHS vision. Those participating in the self-organizing efforts of the Learning Health Community are bonded together by their shared determination to realize the LHS and their common belief in the consensus LHS Core Values that serve to underpin it. (Journal of AHIMA, May 2014) The ten Core Values of the Learning Health Community are described at [www.learninghealth.org](http://www.learninghealth.org). In summary, these values are:

- Person-Focused
- Privacy
- Inclusiveness
- Transparency
- Accessibility
- Adaptability
- Governance
- Cooperative and Participatory Leadership
- Scientific Integrity
- Value