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

Presentation to the HIMSS Center for Patient and Family-centered Care

November 12, 2014

Background to Current Activities

Core Values Underlying a National-Scale, Person-Centered Continuous *Learning Health System* (LHS)

Developed at the May, 2012 Learning Health System Summit

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.

Core Values Underlying a National-Scale Person-Centered Continuous *Learning Health System* (LHS)

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.

Core Values Underlying a National-Scale Person-Centered Continuous *Learning Health System* (LHS)

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.

65 Endorsements of the LHS *Core Values** (As of 10/28/2014)

NCHICA
Lewin and Associates LLC
Ursus Technologies (SDVOSB)
patientslikeme
Minnesota e-Health
ACP
MedDATA Foundation
MINNESOTA MDH DEPARTMENT of HEALTH
Diogenec Group
SANOFI
GEISINGER HEALTH SYSTEM
LAMBDA SOLUTIONS
Peachy
SecureHealthHub, LLC
JOHNS HOPKINS MEDICINE
INHS
Biovista
ANA AMERICAN NURSES ASSOCIATION
GPII
AZZLY One Click Patient Care Management
SIEMENS Siemens Health Services
VUHID
THINKWISE HEALTH
Open Health Tools
TEXAS eHEALTH ALLIANCE
THE CDI GROUP
ADVANCED INSTITUTE
Intermountain Healthcare
NorthShore University HealthSystem
HealthCore
WELLPOINT
vitaTrackr
AMIA
HEALTH
M
AHIMA American Health Information Management Association
CDISC
National eHealth Collaborative
HIMSS transforming healthcare through IT
Imperial College London Department of Primary Care and Public Health
CRITICAL PATH INSTITUTE
Rhode Island Quality Institute
Open mHealth
oz systems
Duke Clinical Research Institute DUKE UNIVERSITY MEDICAL CENTER
The Center for Learning Health Care
e-Patient Dave A Voice of Patient Engagement
American Academy of Pediatrics
Genetic Alliance
HL7 INTERNATIONAL
MOSAICA PARTNERS
2311
COUNT US IN
Harvard Pilgrim HealthCare
ALTARUM INSTITUTE
DANA-FARBER CANCER INSTITUTE
ONS
RightCare SOLUTIONS
ASCO
gsk GlaxoSmithKline
ANI
sas
University of Pittsburgh
GE Healthcare IT
chip
Epic
SCILHS
Medical Advocacy Mural Project
Let's change the "face" of healthcare.

*To be included on a Learning Health Community public website that will list all organizations that have endorsed the LHS *Core Values*.

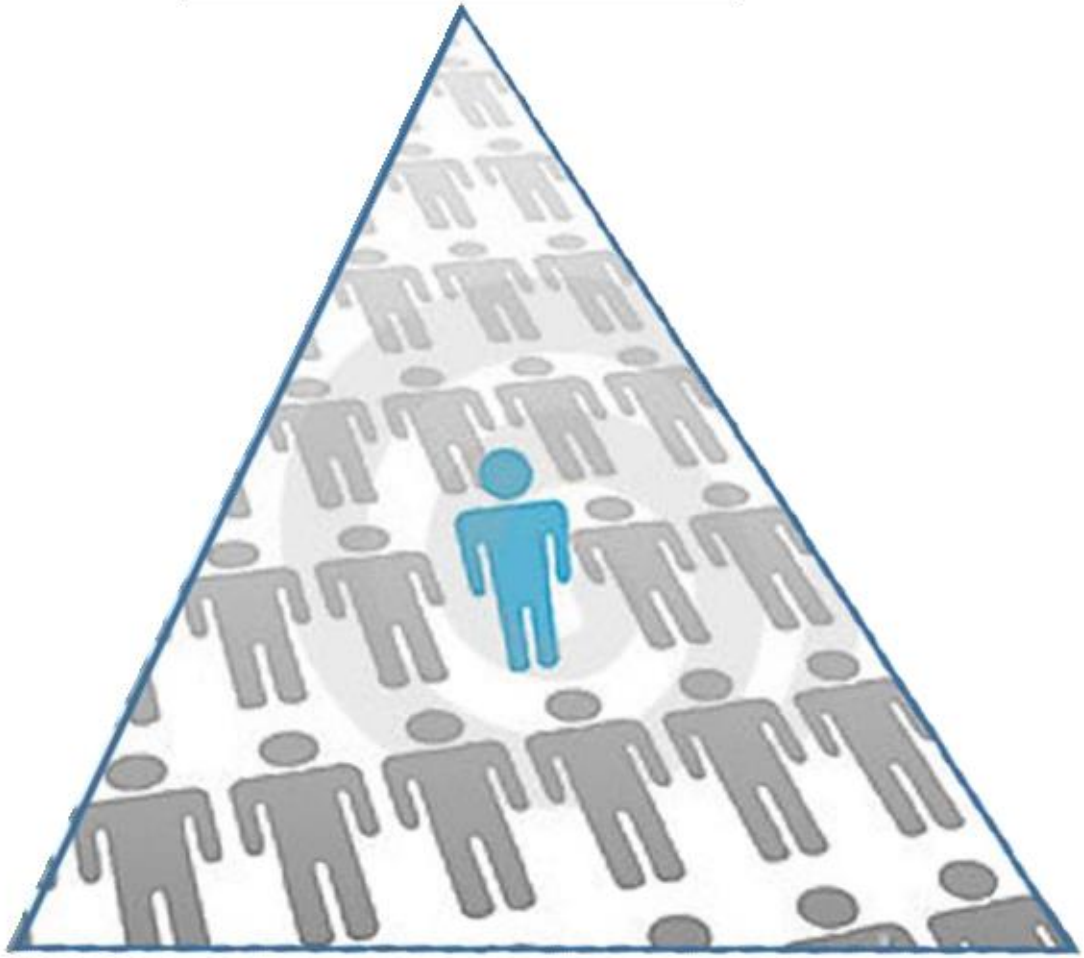
The Learning Health Community:
A Grassroots, Self-Organizing, Multi-Stakeholder Movement

LHS Components

The Learning Health System:

Improving Personal and Population Health through Knowledge

Community
Data on Individuals & Populations
Problem Definition
Research Plan



Governance
Data Use
Policies & Procedures
Standards Adoption

Education
Communications
Publications
Messaging

Technical
Aggregation
Analysis
Security

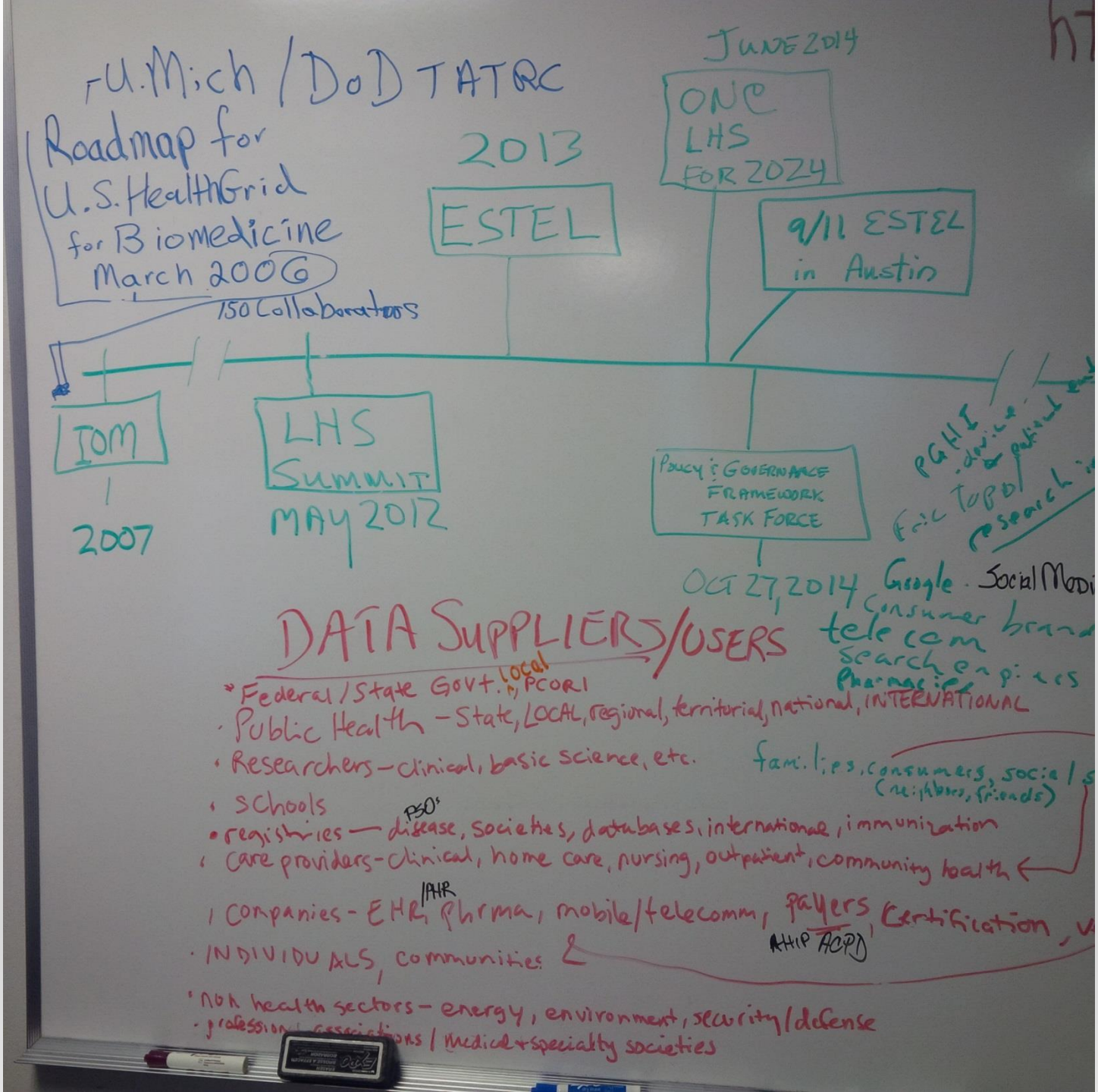
Policy & Governance Initiative

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**, comprising 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.

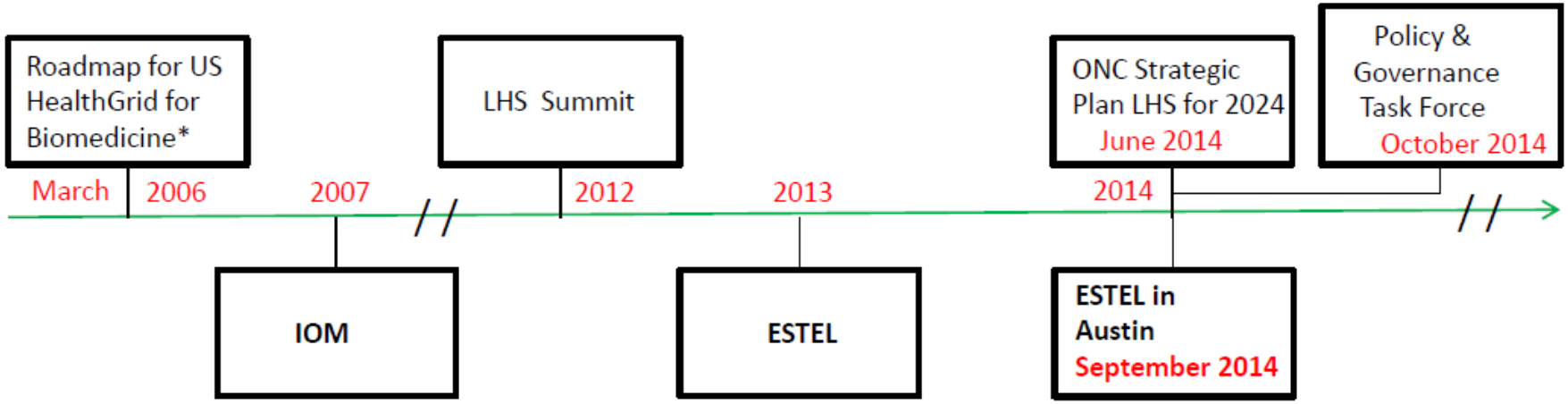
Initial Meetings Oct. 26-27, 2014
NCHICA, Research Triangle Park, NC

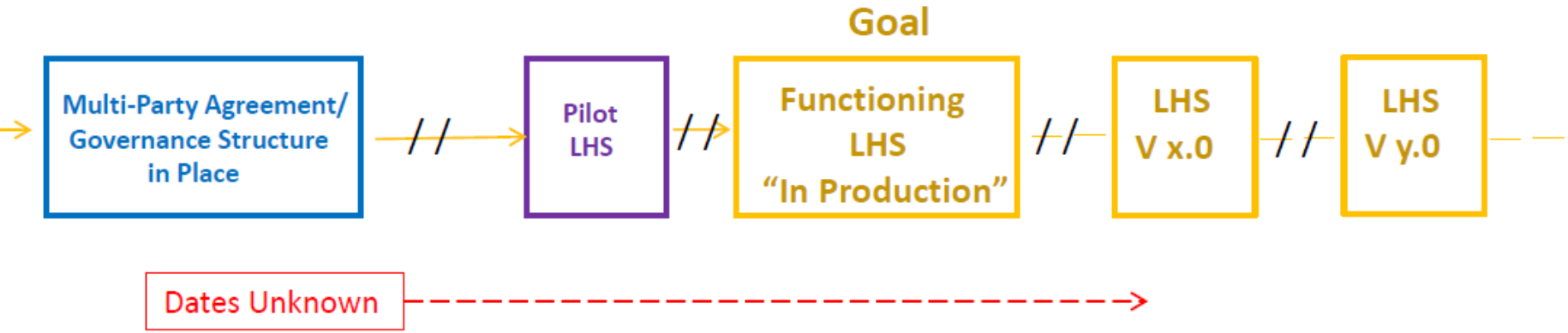
EXIT
A Whole New World
The Art of the Possible
Holly Jarman
Nora Belcher
Vera Betts
Stephanie Bryant
Robert Webster
LabCorp


U.Mich / DoD TATRC
Roadmap for U.S. HealthGrid for Biomedicine March 2006
150 Collaborators
2013
ESTEL
JUNE 2014
ONC LHS FOR 2024
9/11 ESTEL in Austin
IOM
2007
LHS SUMMIT
MAY 2012
POLICY & GOVERNANCE FRAMEWORK TASK FORCE
OCT 27, 2014
DATA SUPPLIERS/USERS
Federal/State Govt. local, PCORI
Public Health - State, LOCAL, regional, territorial, national, INTERNATIONAL
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/telecomm, payers, certification
INDIVIDUALS, communities
non health sectors - energy, environment, security/defense
professional associations / medical + specialty societies
families, consumers, social (neighbors, friends)
Google
telecom
search engines
Pharmacies

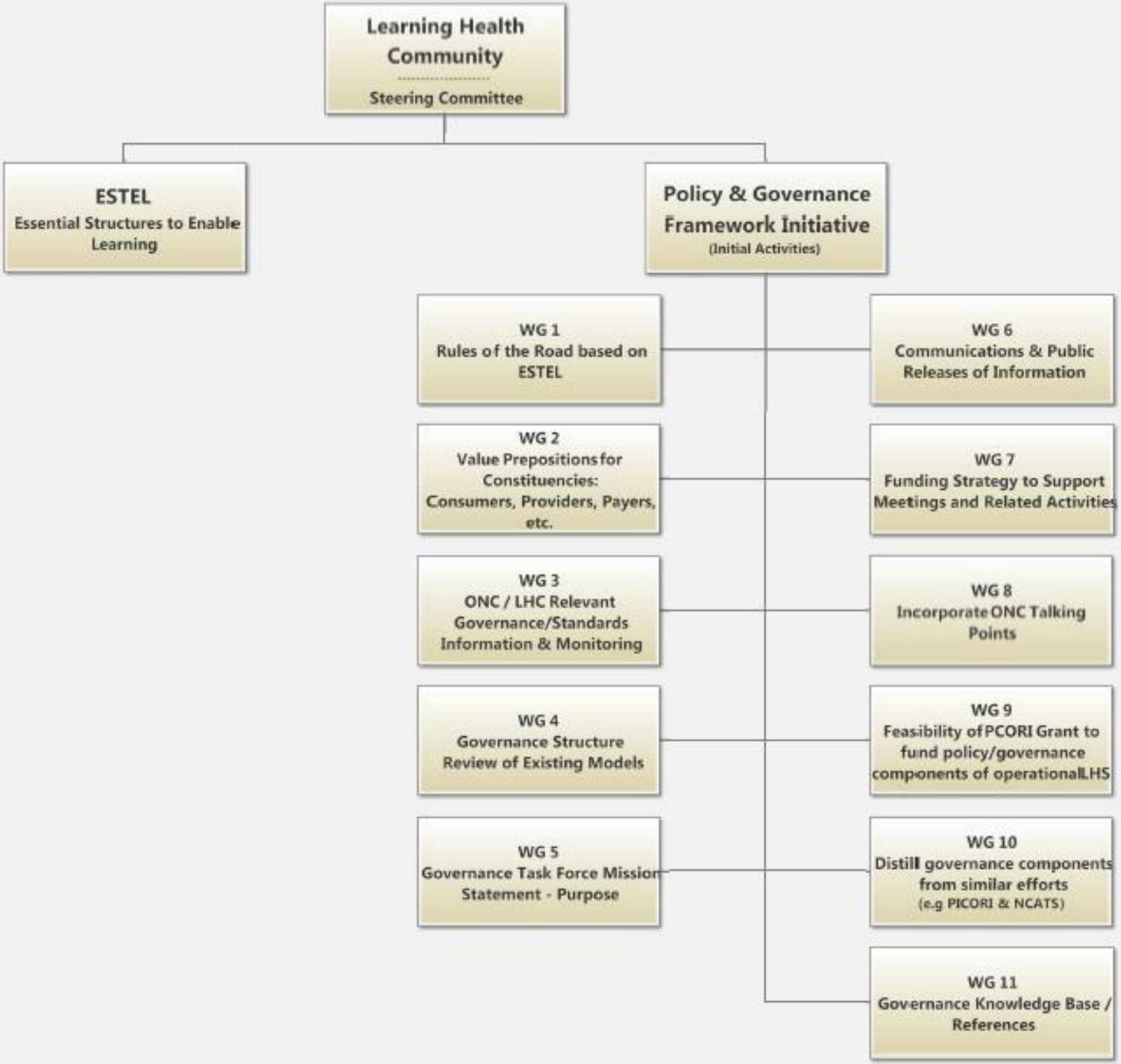
DATA SUPPLIERS/USERS
CFO

LHS Timeline – DRAFT FOR DISCUSSION





* U Michigan; DOD TATRC; 150 Collaborators


Learning Health Community
Steering Committee
ESTEL
Essential Structures to Enable Learning
Policy & Governance Framework Initiative
(Initial Activities)
WG 1
Rules of the Road based on ESTEL
WG 2
Value Prepositions for Constituencies: Consumers, Providers, Payers, etc.
WG 3
ONC / LHC Relevant Governance/Standards Information & Monitoring
WG 4
Governance Structure Review of Existing Models
WG 5
Governance Task Force Mission Statement - Purpose
WG 6
Communications & Public Releases of Information
WG 7
Funding Strategy to Support Meetings and Related Activities
WG 8
Incorporate ONC Talking Points
WG 9
Feasibility of PCORI Grant to fund policy/governance components of operational LHS
WG 10
Distill governance components from similar efforts
(e.g PICORI & NCATS)
WG 11
Governance Knowledge Base / References

Contacts

Joshua C. Rubin, JD, MBA, MPH, MPP
Program Officer for Leaning Health System Initiatives
Department of Learning Health Sciences
University of Michigan Medical School
josh@joshcrubin.com

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

http://www.learninghealth.org