LHC – ESTEL Meeting
16-17 September 2013, Duke

Attendees: Chuck Friedman (U of Michigan), Landen Bain, (CDISC), Josh Rubin (U of Michigan as of October), Sarah Davis (UCSF), Amy Abernethy (Learning Healthcare, Duke), Holt Anderson (NCHICA), Rick Sax (Quintiles), Rich Elmore (Allscripts), Marcy Harris (U of Michigan), Shelley Price (HIMSS), Hunt Blair (HHS/ONC), Tom Oniki (Intermountain Healthcare), Ed Hammond (Center for Health Informatics, Duke), Jeff Brown (Harvard), Michael Park (Duke), Sarita Wahba (PCORI), Eric Brinsfield (SAS), Becky Kush (CDISC), Ken Pool (Oz Systems), Theo Arvanitis (University of Birmingham, UK), Erin Grace (AHRQ), Frank Rockhold (GSK), John Mattison (Kaiser Permanente)

Meeting Notes
Attendees introduced themselves, after which Dr. Chuck Friedman presented an opening set of slides to frame the purpose of this meeting of the Learning Health Community Essential Standards to Enable Learning (ESTEL) initiative. (Please refer to the Friedman slides.) Background on ESTEL to date was provided by Becky Kush. (Please refer to the Kush slides.)

Based upon discussions at the 31 July ESTEL meeting held at IOM, Landen Bain then set the stage for the discussions to take place for the remainder of this meeting. The theme was to use several initiatives as examples of defining a minimum set of standards/requirements in a narrow neck/waist (picture an hourglass) while allowing for and encouraging innovation at the two ends – one for tools and one for the ‘system’. Concentric circles were drawn to envision this at the 31 July ESTEL meeting, but the hourglass and the history of the Internet resonated the best as an analogy.

The Hourglass Model: World Wide Web

The narrow neck of the hourglass defines a small set of core abstractions and protocols (e.g. TCP and HTTP, HTML) onto which many different high-level behaviors can be mapped (the top of the hourglass), and which themselves can be mapped onto many different underlying technologies (the base of the hourglass). By definition the number of protocols defined at the neck must be small.
In our architecture, the neck of the hourglass consists of Resource and Connectivity protocols, which facilitate the sharing of individual resources. Protocols at these layers are designed so that they can be implemented on top of a diverse range of resource types, defined at the Fabric layer, and can in turn be used to construct a wide range of global services and application-specific behaviors at the Collective layer.

*The Anatomy of the Grid, Kesselman*

With respect to the Essential Standard to Enable Learning for an LHS, the following diagram provided a foundation for discussion during this meeting, in addition to guidance for the breakout groups that took place the following day. (See subsequent notes for the output from three breakout groups on 17 September.)

The Hourglass Model for ESTEL (see below) was depicted with The Fabric (‘diverse range of resource types’) as the Healthcare Data at one large end; the Neck (‘resource and connectivity protocols’) in the middle as ESTEL; The Collective (‘a wide range of global services and application-specific behaviors’) was at the other end referencing Tools for the LHS. (Please refer to the slides from R Kush and Landen Bain.)

The rest of the afternoon was devoted to an excellent panel of presenters, who shared experiences with current projects that are related to LHS and specifically to the standards as enablers in these projects/initiatives. Holt Anderson moderated the panel. (Please refer to Anderson slides as a collection of those for the entire panel.) Presentations were made by the following:

- PCORI Infrastructure – Sarita Wahba
- HHS/ONC – Hunt Blair
- ONC Structured Data Capture Initiative – Ken Pool
Phrases that ‘stuck’ in describing these presentations and the goals of the LHC-ESTEL initiative included the following (apologies for not including those who should be given credit):

“Silo-busting” “Going from Big Data to Big Change” “Knowledge Sharing”

Breakout Groups on 17 September were charged with envisioning the scope and shape of the essential standards to enable a Learning Health System (without specifying any particular standards). Specifically, they were asked to:

1) Consider what an LHS needs to be able to do...the capabilities that are needed.

2) Identify the categories, classes or types of standards that need to be in the narrow neck of the funnel – Essential Standards to Enable Learning.

The notes below are primarily photographs from the white boards for the breakout groups and some notes for Group 2. These were synthesized during the joint session at the end of the meeting. Participants were (and are) encouraged to assist in refining the language used to describe the conclusions from this ESTEL meeting as they will serve as a foundation for future ESTEL work and meetings.

Breakout Group 1 Drawings and Notes:

![Diagram of Essential Standards to Enable Learning](image-url)
Breakout Group 2 Charting and Notes:

Break-out Group 2: ESTEL: Learning Health System (9/17/13)
Mental Model (initial individual review):

1) Promote learning activities are a moral imperative (Ruth Faden’s article) in health care. Not just delivery of knowledge but access to data to improve health care delivery and outcomes. Self-management, safety, delivery, policy/stewardship of resources ($, personal). Enable behavior changes. Ethical change needed to achieve a true learning system (social, individual, technology).
   a. New ethical framework, data sharing (data donation).
   b. Enable learning activities

2) Bi-directional pathway for information to feed, data qualified and used for various purposes. Allow individuals to access data. Feedback loop for learning.
   a. Easier to get data in and out of system

3) All data (financial, practice quality, outcomes, operational, etc) is currently a closed system, hard to intake outside data (best practices from outside). Federated system that allows to push data back out to others (sharing of knowledge). Rapid/real-time analytics at POC.
4) Consumer Reports like access for patients to determine best care for them.
   a. Transparency with data

5) Making data access easier, access to knowledge easier, for all various audiences, with feedback loop.

**Group Discussion, Focus of LHS Data Standards:**

*Horizontal focus* (rather than vertical):
Read standard, transport standard, storage standard (index and normalize).

**Interaction Profile** (central node that the standard is created on). Contract explicating who ensures quality, fitness for purpose). 3 Sub-Nodes that cover:

1) Data Access & Exchange
   a. Interaction Profile (standardize contract between parties: verifies fit for purpose (shared or consumed)
   b. Data Exchange/Query
   c. Data Model, Terminology Standards: HL7, CCDA, DIMI, DICOM, CDISC, SDTM, CSHARE
   d. Timeliness
   e. Storage/Archive
   f. Governance
   g. Transport, Security (also applies to Trust)

2) Trust
   a. Trust in Data
      i. Traceability
         1. ODM audit trail (responsibility falls to original source or share with consumer to judge for themselves)
      ii. Transparency
         1. Measures of timeliness
         2. Prevalence
         3. SKOS
         4. Composition of cohort/population aggregation (demographics,
      iii. Quality
         1. ‘Patient Matching’, automated unique patient identification, linking
         2. Data Models/Terminology
         3. Data Quality Framework standards
         4. Data Management, how would standards help, best practices
         5. Data correction/changes
      iv. Complete/Accurate Data (standards can dictate this but could define detection-corrections/changes/updates)
   b. Governance

3) Knowledge (this area represents tools and innovation at one end of the hourglass)
   a. Representation
   b. Analytics

*Standards are de facto Certification*
Breakout Group 3 Drawings and Notes:

- **ESSENTIAL STANDARDS**
- **TO ENABLE LEARNING**

| 1. DESCRIPTION OF POLICY-COMPLIANT ARCHETYPICAL QUERIES |
| 2. QUERY/RESPONSE ENVELOPE |
| 3. DATA CHARACTERISTICS |
| 4. DESCRIPTION OF PARTICIPANTS |
| 5. *METADATA [SEMANTIC WEB] |
| 6. SIMPLE REFERENCE MODEL |

* Process & Governance needed to promote 4, 5, 6 to the neck [- - -]

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LHC-ESTEL 16-17 September 2013
Final Discussion Session

An effort was made to synthesize the observations and recommendations from the three groups. It seems as though there were three areas or themes that had commonalities across the groups. The areas below are key in defining the standards that could be in the cross-section of the hourglass neck. Process and governance will be necessary to promote these to the neck, and standards will need to be identified through a consensus-based process. However, the groups were advised to refrain from naming standards at this point.

1) Participants/Interaction Profile/Authentication
This area represents the relationships and assurances that identify and profile those who are interacting in some manner (such as exchanging); the data must be trusted and the data being exchanged or accessed must be fit for purpose. There are varying levels of acceptable quality, depending upon the purpose or use case. The connections or resources are not necessarily 1:1; they could certainly be 1: many. They could represent a wide range of participants, e.g. patients, institutions or organizations, caregivers, clinicians or others.

2) Metadata/Data Access/Data Exchange/Interactions
This area defines the metadata and the data access or exchange and the interactions that may occur. This might be like the semantic web for the internet. The interactions may involve query metadata and anticipated responses, research case report forms and valid values for the fields, an adverse event form and anticipated metadata for responses and so forth. The data is a resource. There may be a push or a pull relationship. Data may come from various sources, including patient using hand held devices, clinicians using EHRs, researchers using EDC tools, databases or others.

3) Data Model/Data Characteristics
An “Ultra-simple, Ultra-small reference model” was recommended. The data model should canonize information in a relationship between data points. There should schema-agnostic data representation and subjective attributes. Data quality is subjective (depending on the purpose or use case – see 1 above); however these are objective data characteristics.

- Knowledge representation and analytics are facilitated with tools, which should be open for innovation on one end of the hourglass, not in the narrow neck.
- The feedback loop that will complete the circle for the Learning Health System will require analytics and representation.
- Ultimately, the goal is for the Whole LHS to have an impact on health and healthcare (patients and people).
Additional broader suggestions for ESTEL:

- Need a glossary, agreed-upon terminology
- At some point identify 7 data elements for which we can get agreement across research and healthcare
- Need a business architecture (vs. technical architecture)
- Need a maturity model for progress over time
- Distinguish between the whole LHS and ESTEL
- Identify what is in scope and out of scope for ESTEL
- Define the bare minimum that is necessary at the bottle neck itself, Simple and implementable
- Look at the intersection with standards for structured data capture initiative
- Consider the feedback loop to patients
- Identify reference implementations
- Market enablement – look at from own self-interest, what will empower one’s organization to do more?

Idea of scaling Query Health as the solution and scaling PopMedNet – likely not a grassroots approach to arrive with a solution too soon

**Lessons** from the financial sector/banks that standardized on dollars/cents/credits/debits/etc. **Conversations with Dee Hock** (founder of VISA): cannot force this and cannot let any entity drive it or be perceived as driving it – must be “Chaordic”

**Agreed Next Steps:**

Develop a consensus statement specific to ESTEL (group believes working on these several ESTEL initiatives will advance our nation toward realizing an LHS that embodies the Core Values of the LHS)

Develop the figures and notes into a document with the hourglass/Internet as the analogy (attendees requested to send additional descriptions of the figures/notes to Becky)

Develop a Communication/‘marketing’ component

Bring additional stakeholders into the LHC, into ESTEL work

Follow up with a call in about a month to keep move things forward
Addendum – Holt Anderson’s depiction of the LHS