Data Standards for Electronic Health Records

Data Standards in Clinical Trials: Maximizing Innovation by Standardizing
October 19, 2012

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Chief Science Officer & Director, Office of Science & Technology
Improving patients’ experience of care within the Institute of Medicine’s 6 domains of quality: Safety, Effectiveness, Patient-Centeredness, Timeliness, Efficiency, and Equity.

Keeping patients well so they can do what they want to do. Increasing the overall health of populations: address behavioral risk factors; focus on preventive care.

Lowering the total cost of care while improving quality, resulting in reduced monthly expenditures for Medicare, Medicaid, and CHIP beneficiaries.
HITECH Framework: Meaningful Use at its Core

- Regional Extension Centers
- Workforce Training
- Medicare and Medicaid Incentives and Penalties
- State Grants for Health Information Exchange
- Standards & Certification Framework
- Privacy & Security Framework

ADOPTION

MEANINGFUL USE

EXCHANGE

Improved Individual & Population Health Outcomes
- Increased Transparency & Efficiency
- Improved Ability to Study & Improve Care Delivery
Meaningful Use Takes Off

- **52% percent** of office-based physicians intend to take advantage of EHR incentives
- The percentage of primary care providers who have adopted EHRs in their practice has **doubled from 20% to 40% between 2009 to 2011**
- ONC’s Regional Extension Centers (RECs) have signed up more than 100,000 primary care providers
- This means that *roughly one third* of the nation’s primary care providers have committed to meaningfully using EHRs by partnering with their local REC. Momentum is *building*!
- Hospital adoption has more than doubled since 2009, increasing from 16% to 35%
- Most (85%) of hospitals intend to attest to Meaningful Use by 2015
Though clinical research is not a specific part of Meaningful Use...

– Making patient data electronic creates new opportunities for clinical trials management

– Terminologies and standards that will be critical are being developed/harmonized in the S&I Framework

– MU3 will focus on developing a “learning health care system” – clinical trials plays an important role
ONC’s Guiding Principles

• Interoperability is a *journey*, not a destination

• Leverage *government as a platform* for innovation to create conditions of interoperability

• Health information exchange is *not one-size-fits-all*

• Build in *incremental steps* – “don’t let the perfect be the enemy of the good”
Enable stakeholders to come up with simple, shared solutions to common information exchange challenges.

Collaborate with federal agencies to coordinate federal health IT priorities as manager of Federal Health Architecture.

Support Innovation through SHARP program, Innovation/Challenge Grants, and interfacing with international Standards community.

Curate a portfolio of standards, services, and policies that accelerate information exchange.

Teams convened to solve problems

Coordinate Federal Partners

Solutions & Usability

R&D
What is the S&I Framework?

• The Standards and Interoperability (S&I) Framework represents one investment and approach adopted by the Office of Science & Technology (OST) to fulfill its charge of prescribing health IT standards and specifications to support national health outcomes and healthcare priorities.

• The S&I Framework is an example of “government as a platform”—enabled by integrated functions, processes, and tools— for the open community of implementers and experts to work together to develop and harmonize health information exchange standards.
Why the S&I Framework Approach?

• **S&I Framework Approach:**
  ▪ Creates a collaborative, coordinated incremental standards process,
    • Guided by ONC, with input from Federal Advisory Committees,
    • Enabled and led by the an open community of industry participants who are interested in solving real world problems

• **Value created through this approach:**
  ▪ Solves real-world issues to enable health information exchange
  ▪ Harnesses the expertise and passion of the community to solve problems
  ▪ Empowers the community to create the best solutions for interoperability and standards adoption
ONC’s Standards “Stack”

**Vocabulary & Code Sets**
How should well-defined values be coded so that they are universally understood?

**Content Structure**
How should the message be formatted so that it is computable?

**Transport**
How does the message move from A to B?

**Security**
How do we ensure that messages are secure and private?

**Services**
How do health information exchange participants find each other?
## Standards Applicability

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Vocabulary &amp; Code Sets</th>
<th>Content Exchange / Utilization</th>
<th>Transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td><strong>OMB Race/Ethnicity ISO 639-2 (constrained)</strong></td>
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<tr>
<td>Problems</td>
<td><strong>SNOMED CT + US ext</strong></td>
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<tr>
<td>CDS</td>
<td><strong>SNOMED CT + US ext</strong></td>
<td><strong>HL7 Infobutton + IGs</strong></td>
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<tr>
<td>Smoking Status</td>
<td><strong>SNOMED CT + US ext</strong></td>
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<tr>
<td>Family Health History</td>
<td><strong>SNOMED CT + US ext</strong></td>
<td><strong>HL7 Pedigree</strong></td>
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<tr>
<td><strong>Patient Ed Resources</strong></td>
<td><strong>SNOMED CT + US ext</strong></td>
<td><strong>HL7 Infobutton + IGs</strong></td>
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<tr>
<td><strong>ToC – receive, display, &amp; incorporate</strong></td>
<td><strong>SNOMED CT + US ext RxNorm</strong></td>
<td><strong>CCD/C32</strong></td>
<td><strong>Applicability Statement for Secure Health Transport</strong></td>
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<tr>
<td></td>
<td><strong>Consolidated CDA</strong></td>
<td><strong>CCR</strong></td>
<td><strong>AppState + XDR/XDM</strong></td>
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<td><strong>Consolidated CDA</strong></td>
<td><strong>SOAP RTM + XDR/XDM</strong></td>
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## Standards Applicability (cont.)

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<tr>
<td><strong>ToC – Create &amp; Transmit</strong></td>
<td>[Common MU Data Set]</td>
<td>Consolidated CDA</td>
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<td>ICD-10-CM</td>
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<td>AppState + XDR/XDM</td>
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<td>CQM Import</td>
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<td>QRDA Category I</td>
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<tr>
<td>CQM e-Submit</td>
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<td>View, download, transmit to 3\textsuperscript{rd} party</td>
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<td>Consolidated CDA</td>
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<tr>
<td>Clinical Summary</td>
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<td>Immz Reporting</td>
<td>CVX</td>
<td>HL7 2.5.1 + IGs</td>
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<tr>
<td>Syndromic Surveillance</td>
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<td>HL7 2.5.1 + IG (inpatient only)</td>
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<td>HL7 2.5.1 + IG</td>
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<tr>
<td>Cancer Registry</td>
<td>SNOMED CT + US ext LOINC</td>
<td>CDA R2 + IG</td>
<td></td>
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# S&I Initiative Portfolio Snapshot

## Direct Project (S&I Archetype)

### Transitions of Care
- **Pilots Underway**

### Lab Results Interface
- **2nd IG Ballot Publication (4/9/12)**

### Query Health
- **Plan to begin piloting in April 2012**

### Provider Directories
- **Looking at potential pilots and reference implementation**

### Data Segmentation for Privacy
- **Targeting completion of pilot(s) and initial evaluation by September 2012**

### Public Health Reporting
- **Community-Led initiative**

### esMD
- **1st (of 3) use cases consensus-approved; Targeting completion of pilot(s) and initial evaluation by October 2012**

### Longitudinal Coordination of Care
- **Working on Extension of the ToC Use Case for LCC (reuse); Limited Support Initiative**

### Laboratory Orders Interface
- **Use Case Reached Consensus In August 2012**

### Health eDecisions
- **Developing Two Use Cases: Artifact Sharing and Guidance Service**

### Automate Blue Button (ABBI)
- **S&I Community launched August 2012**

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**Putting the I in HealthIT**

## Current S&I Initiatives: Operating Metrics

### How long has it been?

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Framework Launch Date</td>
<td>Jan 7, 2011</td>
</tr>
<tr>
<td>First Initiatives Launched</td>
<td>Jan 31, 2011</td>
</tr>
<tr>
<td>Elapsed Time (as-of today)</td>
<td>21 months</td>
</tr>
</tbody>
</table>

### How much have we accomplished?

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td># Use Case Artifacts</td>
<td>33</td>
</tr>
<tr>
<td># Harmonized Segments/Sections</td>
<td>150</td>
</tr>
<tr>
<td># RI/Test Artifacts</td>
<td>64</td>
</tr>
<tr>
<td># Pilots Committed or In Discovery</td>
<td>20+</td>
</tr>
<tr>
<td># Pilot Vendors</td>
<td>25+</td>
</tr>
<tr>
<td># Pilot Healthcare Organizations (e.g. hospitals, HIEs)</td>
<td>35+</td>
</tr>
<tr>
<td>HL7 Ballots</td>
<td>3</td>
</tr>
<tr>
<td># Ballot Comments Received</td>
<td>1,854</td>
</tr>
<tr>
<td># Ballot Comments Resolved</td>
<td>1,479</td>
</tr>
</tbody>
</table>

* Assumes 260 working days per year
Standards Development before the S&I Framework

Disparate entities with a lifecycle ranging from 18-36 months

- Identification of Need for Standard
- Standards Development Organizations
- Testing & Piloting
- Implementation

- Content Standards
- Transport Standards
- Terminology Standards
- Web service Standards
- Privacy Standards

- Interested Stakeholders
  - Government Agencies
  - Early Adopters

- Regulatory Body
- Industry Need
- Changes in Technology

Nationwide Implementers
Standards Development with the S&I Framework
Coordinated entities with a lifecycle ranging from 9-18 months

Identification of Need for Standard → Standards Development Organizations → Testing & Piloting → Implementation

- Common Problem Forum
- Regulatory Body
- Industry Need
- Changes in Technology

Coordination of Resources
- Content Standards
- Transport Standards
- Terminology Standards
- Web service Standards
- Privacy Standards

Interested stakeholders
- Government Agencies
- Early Adopters

Conformance Bodies

Nationwide Implementers
Standards Development with the S&I Framework and future planned improvements

Continuous improvement lifecycle, i.e. agile, to enable market & regulatory relevancy

Identification of Need for Standard

Standards Development Organizations

Testing & Piloting

Implementation

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Common Problem Definition

- Regulatory Body
- Industry Need
- Changes in Technology

Coordination of Resources

- Content Standards
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Interested stakeholders

- Government Agencies
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Conformance Bodies

Nationwide Implementers
Standards Development with the S&I Framework and future planned improvements

Continuous improvement lifecycle, i.e. agile, to enable market & regulatory relevancy:

**S&I Framework:**
- Needs identification
- Standard development
- IG development

**Implementation:**
- Vendors
- Government Agencies
- Early Adopters

**Testing and Implementation Platform:**
- Precertification Testing
- Piloting

Process Flow
- Feedback Loop
Common Data Elements/ Electronic Case Report Form Initiative

Background:

- Electronic health records (EHRs) have the potential to provide useful information for Comparative Effectiveness Research (CER).
- CER is the conduction and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions.
- Many current CER projects rely on data collected in site- or system-specific EHRs.
- The applicability and power of such studies would be increased by the use of structured data definitions – common data elements (CDEs) – that comply with the consensus-derived health data standards established for “Meaningful Use” of EHRs.

In other words, if relevant patient data (e.g., lab test results, marital status, patient-reported depression) were defined and collected in a common way in different CER studies, it would be easier to compare the results of CER studies, and it would be easier to use EHR systems as a source of valid CER data.
Goals:

• Identify and eventually require the use of key CDEs and patient assessment instruments in CER funded by HHS and PCORI,
• Define these CDEs and assessment instruments using standard terminologies and terminology value sets, and
• Develop the infrastructure needed so that CDEs and standardized ways of collecting data for CER are available for use within EHR products.

These efforts will make it easier to conduct CER in diverse community health care settings, by reducing the data collection burden on health care providers and patients and the need to make site-specific modifications to EHR system capabilities in order to enable community participation. They will also ensure that data from different CER research studies can be more easily compared and aggregated.
Learn more at:

ONC website:  
www.healthit.hhs.gov/

S&I Framework wiki:  
http://wiki.siframework.org