Structured Data Capture (SDC)

Update for Digital Learning Collaborative

Farrah Darbouze & Evelyn Gallego
Office of the National Coordinator (ONC)
Office of Science & Technology

May 30, 2014
• SDC Introduction: *what have we accomplished in last six months?*
• SDC Background Recap
• SDC Phase 1 & 2 Implementation Guidance
• SDC Data Element Framework
• SDC Pilot Program
SDC Background: Recap

- Launched in 2013 in collaboration with other Federal Partners: NIH (NLM, NCI), AHRQ, FDA, CMS & CDC
- Key area of focus is enabling the collection of structured data within EHRs to supplement data collected for other purposes to include:
  - Clinical research (Patient Centered Outcomes Research/Comparative Effectiveness Research) (NLM FOCUS)
  - Patient safety event reporting (AHRQ FOCUS) & Adverse Event Reporting (FDA FOCUS)
  - Public Health Reporting (CDC FOCUS)
  - Determination of Coverage (CMS FOCUS)
SDC Standards Focus

SDC Initiative has identified four *standards that specify how EHR systems can capture and store structured data:

1. Standard for the structure/definition of the CDEs that will be used to fill the specified forms or templates
2. Standard for the structure or design of the form or template (container)
3. Standard for how EHRs interact with the form or template
4. Standard to pre-populate and auto-populate form or template with existing patient data
Structured Data Capture Conceptual Workflow

1. Sends request for form/template
2. Form/Template Repository
3. Converts, populates & displays form
4. Fills, stores/transmits structured data
5. Extract, Transform, & Load Data by form/template
Phase 1: SDC Standards
Implementation Guidance

• SDC standards identified for Phase 1 are not ‘new’; most are mature standards being used across industry to meet specific interoperability specifications

• SDC Standards are specified via:
  • SDC Implementation Guide: published March 2014, available for testing
  • SDC IHE Profile: to be published for public comment June 2014; ready for trail implementation in August 2014

Content & Structure
• CDA Consent Directives
• ISO/IEC 11179
• ISO/IEC 19763-13
• IHE DEX

Transport, Security, and Authentication
• IHE RFD
• IHE ATNA
• SOAP
• TLS v1.0 or higher
• SAML
Phase 2: SDC FHIR CDE Definition

- Kicked-off in March 2014; intent was to build on emerging ‘content’ standard FHIR and REST interactions
- Scope is to define HL7 FHIR CommonDataElement Resource that utilizes ISO/IEC 11179-3 syntax with core attributes to facilitate the definition of common data elements
- Also includes development of a mechanism for clinical systems to expose CDEs for research use leveraging existing FHIR Questionnaire Resource
- Draft for HL7 FHIR CDE Resource will be published for comment in Sept. 2014
- DSTU for HL7 CDE Resource and Questionnaire will balloted in January 2015
SDC Data Element Definition Framework

Logical groupings of data elements

Unit of data for which the definition, identification, representation, and permissible values are specified by means of sets of attributes.

Set of characteristics that describe DE and help define, use and maintain DE using ISO1179-3 syntax

Common Data Elements (CDEs) are those DEs that are developed, maintained and used based on commonly agreed upon principles by the user community. CDEs are reusable across a variety of clinical and non-clinical domains.
SDC Pilot Program:
Test & Validation of SDC
Implementation Guidance
SDC Content Workstreams

- Established to validate, test and pilot the SDC Implementation Guidance (IG)
- **Three Workstreams:**
  - **Public Health Tiger Team**
    - Established in Summer 2013
    - Will pilot SDC IG for three use cases: Cancer Reporting, Early Hearing & Case Reporting for Communicable Diseases
  - **Patient Safety Event Reporting & Adverse event Reporting Sub-Workgroup**
    - Established in Feb. 2014
    - Will pilot SDC IG for adverse event reporting from EHRs to AHRQ and FDA
  - **PCOR Sub-Workgroup**
    - Proposed start Summer 2014; focus on clinical research
Aim for Pilot Program

- Bring awareness on available national standards that will facilitate how non-clinical data like patient safety and public health data is collected and reported by EHR systems
- Identify additional content and workflow requirements for reporting
- Provide tools and guidance for managing and evaluating SDC Pilot Projects
- Create a forum to share lessons learned and best practices
- Real world evaluation of SDC Implementation Guide (IG)
  - *Is this implementable? Useable?*
- Harmonize ‘content’ data elements and forms
Why Pilot SDC Standards?

- Demonstrate compliance with CDC, AHRQ & FDA Reporting Requirements
- Increase efficiency of development and maintenance of SDC standards
- **Advance Stage 3 Meaningful Use of EHRs Learning Health System** where patient information can flow securely from EHRs to other systems
- Validate criteria for inclusion in ONC EHR Certification Program
- Reduce data collection burden on health care providers
- Improve comparability of data to better inform research, quality reporting and ultimately, influence patient care
- Contribute to the Public Health & PSO community
- Be recognized as an early adopter
Efficiencies in Reporting to Federal Agencies

- CDC
- VAERS
- FDA
- MedWatch
- AHRQ
- Patient Safety Organization
- Listed PSO
• Step 1: If you are not yet a member of the SDC Initiative, please follow the steps for joining here
  – http://wiki.siframework.org/Structured+Data+Capture+Join+the+Initiative

• Step 2: Join the PSE/AE SWG and/or Public Health Tiger Team
  – http://wiki.siframework.org/SDC+PSE+and+AE+SWG+Signup
  – http://wiki.siframework.org/Public+Health+Tiger+Team

• Step 3: Attend the weekly Meetings
  SDC PSE/AE SWG meets every Monday from 1-2pm ET
  Public Health Tiger Team meets every Tuesday from 2-3pm ET

• Step 4: Participate as a Reference Implementation / Pilot Site…
How Can You Participate?

• SDC Pilots Planning and Actions Document
  – Google Doc (downloadable MS Word version is also available)
  – Also embedded in the wiki on the Pilots Page (scroll down)
    • [http://wiki.siframework.org/Structured+Data+Capture+Pilots](http://wiki.siframework.org/Structured+Data+Capture+Pilots)

---

**SDC Pilots Document**
For anyone who has issues accessing Google Docs, here is a [downloadable MS Word version](http://wiki.siframework.org/Structured+Data+Capture+Pilots) (updated 2014-04-28).

**SDC Pilots Planning and Actions Document**


Contacts: Jenny Brush ([jennifer.brush@esacinc.com](mailto:jennifer.brush@esacinc.com)) and Evelyn Gallego ([evelyn.gallego@siframework.org](mailto:evelyn.gallego@siframework.org))

---

**Pilot Participation Checklist**

- [x] Register as a committed member of the SDC initiative
- [x] Complete the [SDC Pilot Interest Survey](http://wiki.siframework.org/Structured+Data+Capture+Pilots)
- [x] Review the [SDC Overview](http://wiki.siframework.org/Structured+Data+Capture+Implementation+Guidance) and read through the completed [Structured Data Capture Implementation Guidance](http://wiki.siframework.org/Structured+Data+Capture+Implementation+Guidance) to determine
In addition to NIH/NLM, AHRQ and FDA participation in the SDC Initiative, other key stakeholders include:

- CMS
- CDC
- DoD/VA Interagency Program Office
- ASPE
- PCORi
- Standard Development Organizations: IHE, HL7, CDISC
- Vendors: Epic, Allscripts, Siemens, McKesson, Cerner, Greenway, Oz Systems, KBCore, AthenaHealth, Quantros and other RMIS system vendors
Initiative Coordinator: Evelyn Gallego (evelyn.gallego@siframework.org)
Federal Lead: Farrah Darbouze (farrah.darbouze@hhs.gov)
Project Manager: Jenny Brush (jenny.brush@esacinc.com)
Harmonization Support: Hector Cintron (hector.cintron@accenture.com)
Harmonization Lead: Vijay Shah (vshah@jbsinternational.com)

SDC Wiki Page: http://wiki.siframework.org/Structured+Data+Capture+Initiative

Weekly All-Hands Meeting Info (Thursdays):
Time: 3:25pm – 4:30Ppm Eastern
URL: https://siframework1.webex.com/
Dial-In Number: 1-650-479-3208
Access Code: 663 397 496