USE OF INTEGRATING THE HEALTHCARE ENTERPRISE (IHE) STANDARDIZED DATA CAPTURE (SDC) CONTENT PROFILE TO EXCHANGE STANDARDIZED DATA BETWEEN CLINICAL CARE AND CANCER REGISTRIES

NAACCR 2015 Annual Conference
Sandy Jones
June 18, 2015

Cancer Surveillance Branch
Division of Cancer Prevention and Control
Centers for Disease Control and Prevention
Presentation Outline

- Overview of Structured Data Capture (SDC)
- 2015 HIMSS Interoperability Showcase
- 2015 American Society of Clinical Oncologists (ASCO) Interoperability Showcase
- Advantages and Disadvantages of using SDC
Special Acknowledgements

- **College of American Pathologists (CAP)**
  - Richard Moldwin
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  - Jaleh Mirza

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  - Timothy Davidson
  - Jeremy Pine

- **DB Consulting**
  - Shailendra Bajracharya
  - Wendy Scharber

- **CDC NPCR**
  - Wendy Blumenthal
  - Joe Rogers
STRUCTURED DATA CAPTURE (SDC) OVERVIEW
Structured Data Capture (SDC) Initiative

- Launched in 2013 in collaboration with NIH (NLM, NCI), AHRQ, FDA, CMS & CDC
- Uses structured data within EHRs to supplement data collected for other purposes:
  - 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)
Structured Data Capture (SDC) Initiative Standards Focus

- Standard for the structure/definition of the Data Elements that will be used to fill the specified forms or templates
- Standard for the structure or design of the form or template (container)
- Standard for how EHRs exchange the form or template
- Guidelines to pre-populate and auto-populate form or template with existing patient data
Integrating the Healthcare Enterprise (IHE) Structured Data Capture (SDC) Profile

- Developed within the IHE Quality, Research and Public Health (QRPH) Domain
- Enables EHRs or other systems to retrieve a standard form and submit data from the completed form
- Utilizes existing IHE Profiles
- Published for trial implementation in Sept 2014
  - [http://ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_SDC.pdf](http://ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_SDC.pdf)
- Additional Information: [http://wiki.siframework.org/IHE+SDC+Profile](http://wiki.siframework.org/IHE+SDC+Profile)
Structured Data Capture (SDC)  
Form Design and Data Elements

- Single XML schema to support any type of form content and any type of data transmission (XML, HTML, or URI)
- Mapping system that allows use of any type of Data Element (DE) or coding system
- Mapping to DE for cross-form conformance to national standards and codes managed in a central location
Form Templates and Data Elements (DEs) live in public repositories

Some question answer sets (QAS) are mapped to DEs (QAS:DE), and some are not (QAS)

DEs may or may not be mapped to terminology codes and/or local codes

Can map QAS to terminology codes directly in the form template or in an external map
Identifiers can be Mapped to Data Elements (DE) (this is external to the Form Template and optional)

- Mapping tables are maintained with the forms and usually travel with the form in an XML package, but are not required.
- DEs are stored in a repository and can be looked up on demand via a web service.
- DEs are maintained independently of forms.
Semantic Support - SDC Recommendation

- Uses an ISO 11179 Data Element (DE) model
- Avoid mapping directly to terminologies
- Map to the DE level (if it exists)
- If DE does not exist ~ map directly to a code

Using FHIR* principles, we are creating FHIR-based models to support compatible form templates & DEs

(* HL7 Fast Healthcare Interoperability Resources)
SDC Solution Plan:  
In Scope Transactions

• Form/Template Request and Response without Patient data
  • EHR System sends request for *blank* form/template to Form/Template Repository
  • Form/template Repository sends requested *blank* form to EHR System

• Form/Template Request and Response with Patient data
  • EHR System sends request for form/template with *relevant patient data* to Form/Template Repository
  • Form/Template Repository sends form/template with *pre-populated patient data* to EHR system

• **EHR System sends completed** form/template to External Data Repository
Primary Tumor (pT)

- pTX: Cannot be determined
- pT0: No evidence of primary tumor
- pT1: Tum or 5 cm or less in greatest dimension, no extra-adrenal invasion
- pT2: Tum or greater than 5 cm, no extra-adrenal invasion

Adjacent organs include kidney, diaphragm, great vessels, pancreas, and liver.

- pT3: Tum of any size with local invasion, but not invading adjacent organs
- pT4: Tum of any size with invasion of adjacent organs

Note: There is no category of carcinoma in situ (pTis) relative to carcinomas of the adrenal gland.

- pTX: Cannot be determined
Structured Data Capture Workflow

1. Sends request for form/template

2. Sends requested form/template

3. Converts, populates and displays form

4. Fills, stores/transmits structured data

5. Extract, Transform, and Load Data by form/template

Actor Key:
- Filler
- Manager
- External Repository
INTEGRATING THE HEALTHCARE ENTERPRISE (IHE) NORTH AMERICAN (NA) CONNECTATHON
Participating Organizations and Roles

- **Form Managers:**
  - JBS International
  - NCI caDSR
  - USHIK
  - Aegis

- **Form Fillers:**
  - Epic
  - mTuitive
  - GE Healthcare
  - National Health Data System

- **Form Receivers:**
  - CDC NPCR
  - California Department of Health
  - CRG Medical
  - FDA
  - JBS International

- **Form Creators:**
  - CAP
  - NCI caDSR
SDC Forms Used for Testing

- General Demographic Form
  - URI, HTML, XML, and Pre-Pop XML
- CAP Adrenal Form
  - HTML and XML
- NCI Demographic Form
  - HTML and XML
- FDA Form
  - HTML and XML
- Hospital Emergency Response Form (HERF)
  - HTML and XML
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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Public Health Cancer Registry Scenario
Tested at 2015 IHE NA Connectathon

Anatomic Pathology or Genetic Laboratory

Form Filler Requests IHE SDC Form (CAP Checklists)

Lab transmits SDC Form on patient diagnosed with cancer

Clinic/Physician Office (CPO)
Patient presents with symptoms and cancer is diagnosed

Lab transmits SDC Form on patient diagnosed with cancer

CPO transmits HL7 CDA Cancer Reporting document and SDC Form on patient diagnosed with cancer

State Public Health Agency - Form Receiver

Decision Support Tool
Public Health Cancer Registry System
## 2015 IHE NA Connectathon
Successful IHE SDC Testing Results

<table>
<thead>
<tr>
<th>California Department of Public Health</th>
<th>Form Filler</th>
<th>Form Manager</th>
<th>Form Processor</th>
<th>Form Receiver</th>
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</thead>
<tbody>
<tr>
<td>Centers for Disease Control and Prevention</td>
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<tr>
<td>CRG Medical, Inc.</td>
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<td>USHIK (Data Consulting Group, Inc.)</td>
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<td>Epic Systems Corporation</td>
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<tr>
<td>Food and Drug Administration</td>
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<td>JBS International, Inc.</td>
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<tr>
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</table>
IHE Structured Data Capture (SDC) Profile

- Recommendations made to Office of the National Coordinator (ONC) for modifications and enhancements to IHE SDC Profile
- Use of SDC was included in the Notice of Proposed Rule Making for Stage 3 Meaningful Use
- Invited to demonstrate at the 2015 Healthcare Information Management and Systems Society (HIMSS) Interoperability Showcase
HEALTHCARE INFORMATION AND MANAGEMENT SYSTEMS SOCIETY (HIMSS) INTEROPERABILITY DEMONSTRATION
Participating Organizations and Roles

- Optum - Hospital
- Genelex – Genetic Lab
- GE Healthcare – Primary Care Physician
- Epic - Oncologist
- Qvera - Pathologist
- CDC NPCR – Public Health (PH) State Cancer Registry
- California Department of Health – PH Cancer Registry
- JBS International – Form Manager
- NextTrials – Clinical Research
- Infrastructure: Infor, Oracle, Merge, Intersystems, Coretek
Public Health Cancer Reporting Solutions

Patient presents with symptoms and cancer is diagnosed

Clinic/Physician Office (CPO)

Anatomic Pathology or Genetic Laboratory

Pathology Report indicates patient has cancer

Pathology Report indicates patient has cancer

IHE SDC

IHE SDC

IHE SDC

IHE SDC, PRPH-Ca

IHE PRPH-Ca (XDS)

CPO transmits patient data to Public Health Cancer Registry

IHE PRPH-Ca (SDC)

Infrastructure

Public Health Cancer Registry System
2015 ASCO INTEROPERABILITY DEMONSTRATION
Participating Organizations

- ASCO
- ACT.md
- 5AM
- BayesMendel Lab
- mTuitive
- JBS International
- Genospace
- Vanderbilt University Medical Center
- McKesson Specialty Health
- EndoSoft
- CDC NPCR
- University of Michigan Health System
- Lantana Consulting
- College of American Pathologists
Narrator: Patient sees his Primary Care Physician who observes symptoms concerning for colon cancer. Confirmation is obtained by colonoscopy by the consultant gastroenterologist. Colonoscopy report is made available to the PCP. PCP moves ahead to create a care plan.

PCP formulates a care plan with the Patient indicating care goals, instructions, upcoming tests, medications and follow-up plan. PCP suggests that the patient create a Family Health Pedigree next.

Patient creates a family health pedigree document.

Hughes Risk Apps combines family pedigree and risk scores to make recommendations for genetic testing.

Bayes Mendel WebService calculates risk scores.

HL7 Pedigree Model with Genetic Testing Recommendations
mTuitive

Surgical Oncologist performs a resection of the tumor segment. mTuitive demonstrates Operative Note functionality and SDC Pathology Report via JBS.

CDC

Public Health Cancer Registry receives the Cancer Report from the Medical Oncologist, and Pathology & genetic test results from the lab.

Genomic Lab makes genomic testing result on intra-op pathology specimen available to the clinical team.

Genomic Testing Result

Genomic Testing Request

Genomic Testing Result

Genomic Testing Result

Genomic Testing Result

Genomic Lab

HL7 Pedigree Model with Genetic Testing Recommendations

SMART Precision Medicine app compares genomic mutations with the local population.

Vanderbilt University

McKesson

NCCN

Medical Oncologist administers chemotherapy with NCCN-based decision support integrated in the McKesson EMR.

EndoSoft

Medical Oncologist closes the oncologic care of the patient and hands off to PCP. EndoSoft creates summary record (ASCO COTPS) and produces Registry Report.

Epic

Primary Care Physician coordinates follow up care and continues to manage other comorbidities.

Lantana Consulting Group

Nutritionist consulted on the patient’s diabetes tailors a meal plan and monitors blood sugars from a Home Health Device. Lantana’s Camara tool allows the Nutritionist to send CCD documents to the PCP.

Patient, Oncologists, and other Caregivers also receive a copy of the Clinical Oncology Treatment Plan and Summary.
## eMaRC Plus Prototype

Receiving IHE SDC-Compliant Form

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</tr>
<tr>
<td>Deep Margin/Intraperitoneal mural</td>
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</tr>
</tbody>
</table>
Lessons Learned

- Total of 54 attendees
- Start planning sooner to obtain approved CEU credits and have session published in program
- Broader communication about session
- Physical location of session needs to be closer to main exhibit area
- Break the scenario down into smaller pieces and allow more time for speakers
- Planning for 2016 ASCO Annual Meeting will begin soon
ASCO Interoperability Demonstration
2015 ASCO Interoperability Demonstration
CONCLUSIONS
Advantages of SDC

- International standard
- Included in NPRM MU Stage 3 – ONC oversight
- Forms, schema, and mapping tables maintained and updated in one central location
- Doesn’t matter how Form Filler completes the form (HTML, URI, or XML) – Form Receiver will handle data in same way
- Ability to receive the form data dynamically without knowing anything about the form content – just need SDC schema to validate
- Vendor support with less CAP resources
- Plug and play for vendors once supported
Disadvantages of SDC

- Lack of control
- Changes to standard may take longer to get implemented
- Currently does not fully support the more complex CAP electronic Cancer Checklists
- No current support for rules
Important Links

- **IHE SDC Profile (direct link)**
  - [http://ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_SDC.pdf](http://ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_SDC.pdf)

- **SDC IHE Connectathon Wiki Page**
  - [http://wiki.siframework.org/SDC+IHE+Connectathon](http://wiki.siframework.org/SDC+IHE+Connectathon)

- **IHE Connectathon Information (IHE Website)**
  - [http://www.iheusa.org/connectathon.aspx](http://www.iheusa.org/connectathon.aspx)

- **SDC Wiki (main page)**
  - [http://wiki.siframework.org/Structured+Data+Capture+Initiative](http://wiki.siframework.org/Structured+Data+Capture+Initiative)
Thank you!

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E-mail: cdcinfo@cdc.gov  Web: www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.