Using Structured Data Capture to Enhance Cancer Surveillance Data Collection

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Presentation Overview

- Structured Data Capture (SDC)
- College of American Pathologists (CAP) Cancer Checklists
- Impact of SDC on Cancer Surveillance
- Activities to implement SDC
Structured Data Capture (SDC)
What is Structured Data Capture (SDC)

- An information model to standardize clinical content in forms before entered into EHRs
- An interoperable, computer-readable XML-based mechanism to exchange clinical information using standardized data entry forms (questions and answers)
- A model that supports the creation of standardized clinical datasets for analysis
High-Level Goals of SDC

• Demonstrate interoperable exchange of healthcare forms and their data.
• Develop a technical solution to represent, organize and standardize form content and behavior
• Develop a *computer-readable* form model to create technology-agnostic blueprints for vendors’ data entry forms
• Develop a technical solution to represent best practices for *report* format (e.g., synoptic patterns)
• Enable downstream uses of the standardized data
SDC Cancer Data Workflow

1. Form Designer
2. CAP Cancer Protocols
3. Form Manager and Form Repository
4. State Cancer Registry

Provider Environment
- EHR/Laboratory System

Request a Form
Receive the Partially filled Form
Submit Completed Form

Environment
- Patient
- Doctor

College of American Pathologist (CAP)
Forms and Packages

- **Form**
  - One SDC FormDesign XML file

- **Package**
  - One or more SDC FormDesign templates (XML)
  - One Demographic FormDesign template (optional)
  - Maps to terminologies, data elements etc.
  - Transforms and/or other formatting / styling artifacts
  - Administrative data
Introduction to SDC XML

```
<FormDesign
xmlns="http://healthIT.gov/sdc"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="http://healthIT.gov/sdc SDCFormDesign.xsd"
ID="MyForm1">
  <Header ID="H1"/>
  <Body ID="3d" styleClass="body" [18 lines]
  <Footer ID="F1"/>
</FormDesign>
```

```
<body ID="3d" styleClass="body">
  <ChildItems>
    <Question ID="q1" title="Rating of SDC">
      <ListField>
        <List>
          <ListItem ID="341" title="Answer0"/>
          <ListItem ID="253" title="Answer1"/>
          <ListItem ID="254" title="Answer2"/>
          <ListItem ID="255" title="Answer3"/>
        </List>
      </ListField>
    </Question>
  </ChildItems>
</Body>
```
Identifiers can be Mapped to Data Elements

Form Design Template (ID-T1)

Section (ID-S29)

QAS:DE (ID-Q92)

QAS:DE (ID-Q11)

QAS (ID-Q5)

Section (ID-S23)

QAS:DE (ID-Q39)

QAS (ID-Q30)

Map

Q92 \rightarrow DE123

DE123

SNOMED = ...

LOINC = ...

Answer Items =

a (SNOMED = ...)
b(SNOMED = ...)
c(SNOMED = ...)

Note: The map usually travels with the form in an SDC Package. The DEs live in a DE repository, and can be looked up on demand via a web service. DEs may be maintained independently of forms. Maps, if used, are maintained with the form, but do not need to travel with it.
Where do the answers go?*

This model is particularly well suited to eCC data representation and transmission.
Integrating the Healthcare Enterprise (IHE) SDC Value and Benefits [1]

- Create interoperable clinical standards across the healthcare ecosystem
- Implement published clinical interoperability standards.
- Reduce the data collection burden on health care providers.
- Enable downstream uses of the captured standardized data
- Improve clinical research by leveraging data already in EHRs.
- Contribute to and encourage the use of learning health systems.
- Improve comparability of data to better inform research, quality reporting and ultimately, improve patient care.
Integrating the Healthcare Enterprise (IHE) SDC Value and Benefits [2]

- Contribute to projects which support more effective use of informatics (e.g. registries, cohort identification, and shared data across multiple sites to provider larger research cohorts).

- SDC is vendor, domain, and technology agnostic
  - Form Definitions have to be implementation agnostic and not dependent on display technology e.g. HTML and JavaScript
  - Can be rendered in whatever format the implementer chooses, but referencing the defined elements and attributes in the SDC Form Design Instance document
  - When a vendor supports SDC, vendor can support any SDC Form regardless of content

- The SDC information model is designed to retain the clinical context of data
  - e.g. maintaining relationships associated to form context (e.g. LDCT Lung Cancer Screening Form), body structure, disease states, and time frames
College of American Pathologists (CAP) Cancer Checklists
Link to Protocols on CAP Home Page at WWW.CAP.ORG

A list of Surgical Pathology and Biomarker protocols are provided here.
Creation of Protocols by Pathologists

- Pathologists at College of American Pathologists (CAP) create cancer protocols based on expert knowledge of clinical needs and laboratory practices
- Protocols are disease- and/or site-specific
  - Biopsy, surgical pathology, and biomarker tests
  - Biomarker reports include tests that are usually reported separately from the main anatomic pathology report
  - Include test results, methods, and quality control information
- Protocols are available in Word or PDF documents available at CAP.ORG
- eCC (electronic CAP Checklists) are also available from CAP through a licensing process
Pathologists Licensed to Use CAP eCC in U.S. and Canada
Why has CAP moved to SDC?

- SDC is technically more capable than the original eCC model
  - Expanded metadata set (computer instructions)
  - More compliant with modern healthcare informatics and general programming approaches
  - Standards development process (ONC, IHE)
  - Covers the entire data ecosystem, including standardized content design, data-entry, transmission, storage, aggregation and querying
  - Open source tools
Summary of Steps and Tools

- CAP pathologists create protocol based on practice guidelines, and clinical needs.
- Protocols contain checklists of information included in the biopsy, surgical pathology, or biomarker report.
- Available as Word and PDF documents.

- IT experts use XML to structure the checklists into SDC (Structured Data Capture) Questions and Responses.

- CAP pathologists and IT experts collaborate to create an online form using HTML.
- Browser displays form for pathologist to complete and submit.

- Pathologist’s responses are incorporated in XML form, transmitted to pre-determined physicians, facilities, or registries as needed.
HTML Example: ER Results, XML transformed to HTML rendered by Microsoft Edge Browser

Everything in the Word version is contained in the eCC SDC XML template
eCC/SDC Workflow Review
Benefits of the CAP eCC SDC Templates

- Integrates into pathologist AP-LIS workflow
- Supports and aids the pathologist in the diagnostic process
- Standardizes the collection and reporting of cancer patient data
- Facilitates communication between pathologists, clinicians and cancer registrars
- Helps to advance the pathologist role as chief diagnostician and a leader in the patient care process
- Improves and supports information exchange and data interoperability
- Provides automated access to patient data through work with vendors
Impact of SDC on Cancer Surveillance
Mapping eCC SDC to NAACCR Items

- New 2018 NAACCR biomarker data items (SSDIs) aligned with the CAP templates
- Table maps each relevant SDC response to NAACCR item number (usually a new SSDI) and value
- Some items not relevant to registries -- status of controls, methods, fixation time -- not mapped

<table>
<thead>
<tr>
<th>SDC ID</th>
<th>Response</th>
<th>(NAACCR item #, code)</th>
</tr>
</thead>
<tbody>
<tr>
<td>29604.100004300</td>
<td>ER Positive</td>
<td>(3271,1)</td>
</tr>
<tr>
<td>32075.100004300</td>
<td>% cells w/nuclear positivity 11-20%</td>
<td>(3827,1) and (3826,R20)</td>
</tr>
<tr>
<td>29915.100004300</td>
<td>ER Negative</td>
<td>(3827,0) and (3826,000)</td>
</tr>
<tr>
<td>31072.100004300</td>
<td>Cannot be determined (indeterminate)</td>
<td>(3827,9) and (3826,XX9)</td>
</tr>
</tbody>
</table>
Advantages of eCC SDC to Registries [1]

- Maintenance will be much easier, because CAP is already doing the SME and IT work, and template contents are carefully vetted by committees of recognized experts.
- Interoperability with EHR vendors and others such as pathology software, AJCC, ASCO, and CMS
- Registry can process results from facility registrars the same way as from labs
- Standardized data collection forms will be uniform, simplifying training and processing
- Infrastructure for creating, transmitting, and mapping the messages already exists and is in use for path lab reporting
Advantages of eCC SDC to Registries [2]

- Many anatomic pathology and some major EHR vendors, such as Epic and Cerner, are already supporting this infrastructure for lab reporting.
- Will enable registries to quickly incorporate important new data elements without the usual time lag of several years without precluding the continued use of the current NAACCR flat file format.
- Use of SDC XML can be easily aligned with newly developed NAACCR XML format.
- Offers potential for increased flexibility in accommodating changes in cancer medicine.
SDC Activities
Activities to Implement SDC

- CAP implementation of SDC eCC templates
- California Cancer Registry structured reporting initiatives
- CDC NPCR implementation of SDC in eMaRC Plus and Web Plus
- Cancer Care Ontario implementation of SDC
CAP Implementation of SDC

Implementation:

Licensed eCC users will be required to implement eCC SDC templates beginning January 2019

Use of CAP biomarker templates are not yet required for accreditation

Try it out: 
https://sdt.cap.org/sdcapp/GetForm.aspx
California Cancer Registry Structured Reporting Initiatives

- Phase 1 (Pilot): Feb 2013 – July 2013
  - 2 sites, de-identified, legacy reports (Cerner, mTuitive)
- Phase 2: Feb 2014 – Dec 2014
  - St. Joseph’s Health System (mTuitive)
  - UCSF Benioff Children’s Hospital Oakland (SCC Soft)
  - Real-time transmission of structured pathology reports
- Phase 3: 2015-2017+
  - Associated Pathologist LLC (PathGroup)
  - 3 additional organizations, 7 new labs
  - New site onboarding, maintenance and sustainability
- CA AB 2325 legislation effective on January 1, 2019
  - Labs not required to report using CAP eCC, but many are willing to be in compliance with new legislation
CDC/NPCR Implementation of SDC

- Implemented reporting of CAP eCC data in NAACCR Volume V standard (HL7 2.5.1) from PathGroup Laboratory to state cancer registries
- Developed prototype of eMaRC plus to receive the CAP eCCs in SDC XML format
- Tested and demonstrated use of IHE Structured Data Capture (SDC) Profile to receive CAP eCC pathology and biomarker data in eMaRC Plus
- Development of prototype in WebPlus to use CAP eCC SDC XML biomarker templates to abstract cancer biomarker data for new data items in v18
- Incorporate the CAP eCC SDC XML biomarker forms into the central registry database (CRS Plus)
  - From registrars using Web Plus
eMaRC Plus Prototype for SDC XML reporting
Figure X.4.2.2.2-1: Capture and Submit Pre-Authorization – Process Flow diagram

Location in NPCR Web Plus Biomarker Project:

- Web Plus and eMaRC Plus
- CAP, then CDC in the future
- Web Plus

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Two Use Cases for Completed SDC Biomarker Forms

- **Lab Report**
  - Primary source document
  - Mapped to NAACCR items creating secondary abstract with same information

- **Registrar Report**
  - Secondary source document
  - Values mapped to a complete NAACCR abstract

From eMaRC Plus

From Web Plus
Use of CAP eCC SDC in Web Plus
CCO aims to add synoptic reporting across the care continuum in order to improve care for patients through more integrated report
Synoptic reporting – at CCO Today

**Pathology**
Electronic cancer checklists from the College of American Pathologists

**PROs**
Patient Reported Outcomes

**Imaging**
LDCT for lung cancer screening

**Radiation Therapy**
ALR Data – Radiation Planning/ Treatment Activity
IHE Connectathon – SDC Team

2017

2018
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- DCG / AHRQ: Matthew Chudy
- Epic: John Stamm, Keith Simmons, Andrew Wu...
- FDA: Mitra Rocca
- IHE: Wash U: Steve Moore
- JBS: Vijay Shah
- mTuitive: Colin Murphy, Peter O’Toole, Peter Mello
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Bold signifies a major technical contributor (100+ hours) to SDC development and/or ONC pilot
Questions?
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.

Go to the official federal source of cancer prevention information:  
www.cdc.gov/cancer

For more information on CAP’s biomarker templates  
and for eCC versions visit  
www.CAP.org/cancerprotocols