

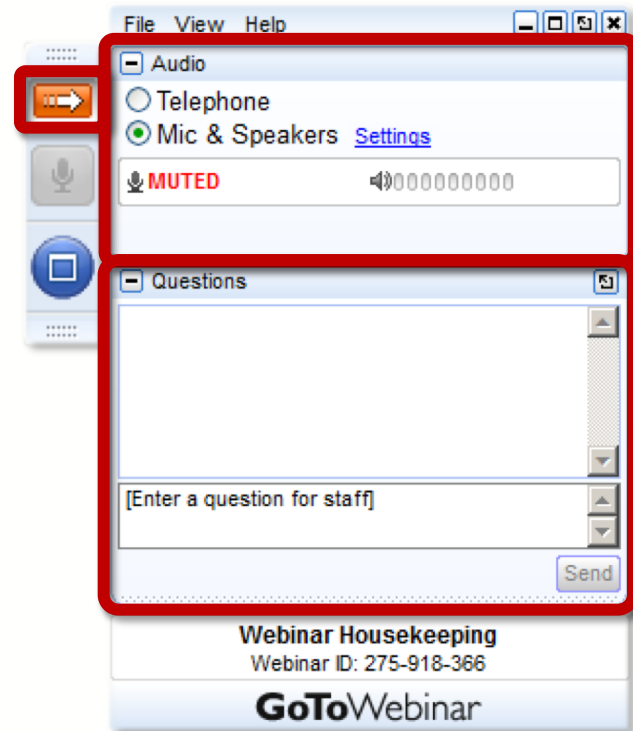


Enhanced Content Testing Program Launch

*Didi Davis, Director of Testing Programs
February 5, 2018*



How Do I Participate?



Your Participation

Open and close your control panel

Join audio:

- Choose “Mic & Speakers” to use VoIP
- Choose “Telephone” and dial using the information provided

Submit questions and comments via the Questions panel

Note: Today’s presentation is being recorded and will be provided within 48 hrs

Problems or Questions? Contact Dawn Van Dyke

dvandyke@sequoiaproject.org or 703.864.4062



Didi Davis
VP, Informatics,
Conformance &
Interoperability



Matt Blackmon
Testing Programs
Engineer



Lisa R. Nelson
Subject Matter
Expert



Agenda

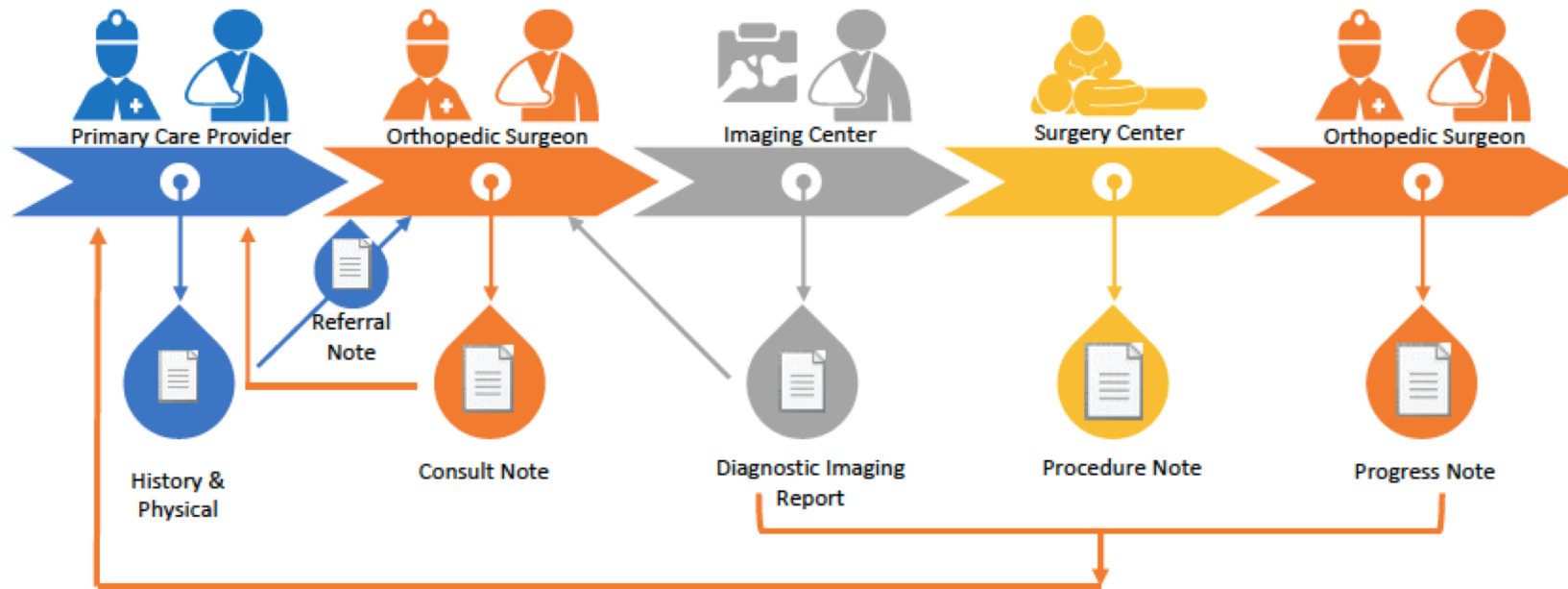
- Background
- New Content Testing Program Details
 - Enhanced Content Testing Documentation Package
 - Content Testing Process
 - Content Testing Tooling
 - Enhanced Content Testing Milestones/Timeline
- Updates for Validation Plan for Qualified Technology Solution
 - QTS to allow for Basic, Intermediate, Advanced levels
- Questions and Discussion

Enhanced Content Testing - Milestones

Milestone Descriptions	Target Date	Status
Present to CC for Review/approval	11/15/2016	Completed
Participant Input (Post draft to eHealth Exchange Wiki)	11/15/2016	Completed
Participant Input Informational Call (Review documentation)	12/02/2016	Completed
30 day notice to Participants	12/02/2016	Completed
30+ day Objection Period Ends	01/10/2017	Completed
Effective Date	01/11/2017	Completed
eHealth Exchange Enhanced Content Testing Program Launch	02/05/2018	Completed
Testing Workgroup Feedback to HL7/ONC	Ongoing	Ongoing

Use Cases - C-CDA: Exchanging the Patient's Story

- Today, most of the clinical data exchanged by systems leverages **ONLY** the CCD
- Many documents are not created by a human but by a machine on demand when queried. Data should be exchanged using appropriate document types.



<http://www.himss.org/library/c-cda-documents-building-blocks-meaningful-exchange>

Why is using the right type of document important?

- Each CDA Document is designed to address a specific purpose
 - Use Cases should be reviewed to determine appropriate documents for use to support optimal patient care
 - Documents need to fit the situation
 - Share information that is relevant and pertinent
- Establish the right context for the information being shared
 - Information about multiple encounters
 - Information about a single encounter
 - Information about a service(s) within an encounter
 - Information that is related to a specific order
 - Patient generated information vs. Clinician or System generated data

	Admission Diagnosis	Admission Meds	Advance Directive	Allergies & Intolerances	Anesthesia	Assessment & Plan	
Assessment	Chief Complaint Reason for Visit	Chief Complaint	Complications	Course of Care	DICOM Object Catalog	Discharge Diagnosis	Discharge Diet
Discharge Medications	Encounters	Family History	Fetus Subject Context	Findings	Functional Status	General Status	Goals
Health Concerns	Health Status Eval/Outcomes	History Past Illness	History Present Illness	Hospital Consultations	Hospital Course	Hosp. Disch. Instructions	Hosp. Disch. Physical
Hosp. Disch. Studies Sum.	Immunizations	Implants	Instructions	Interventions	Medical (Gen) History	Medical Equipment	Medications Administered
Medications	Mental Status	Nutrition	Objective	Observer Context	Operative Note Fluids	Op Note Surgical Proc.	Payers
Physical Exam	Plan of Treatment	Planned Procedure	Postoperative Diagnosis	Postprocedure Diagnosis	Preoperative Diagnosis	Problem	Procedure Description
Procedure Disposition	Procedure Est. Blood Loss	Procedure Findings	Procedure Implants	Procedure Indications	Procedure Specimens	Procedures	Reason for Referral
Reason for Visit	Results	Review of Systems	Social History	Subjective	Surgery Description	Surgical Drains	Vital Signs

<http://www.himss.org/library/c-cda-documents-building-blocks-meaningful-exchange>

Transfer Summary

REQUIRED:	OPTIONAL:		
Allergies & Intolerances	Admission Diagnosis	Functional Status	Payers
Assessment	Admission Meds	General Status	Physical Exam
Medications	Advance Directive	History Past Illness	Procedures
Problem	Assessment & Plan	History Present Illness	Review of Systems
Reason for Referral	Course of Care	Immunizations	Social History
Results	Discharge Diagnosis	Medical Equipment	
Vital Signs	Encounters	Mental Status	
	Family History	Nutrition	

CCD

REQUIRED:	OPTIONAL:	
Allergies & Intolerances	Advance Directive	Payers
Medications	Encounters	Plan of Treatment
Problem	Immunizations	
Procedures	Family History	
Results	Functional Status	
Social History	Medical Equipment	
Vital Signs	Mental Status	
	Nutrition	

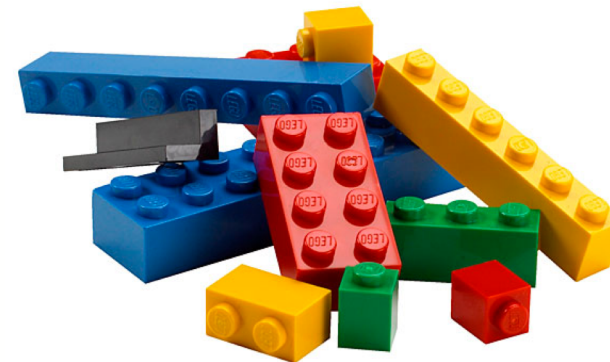
C-CDA R1.1 (9 Types) and R2.1 Document Types (12 Total)

C-CDA R1.0/R1.1

- Consultation Note
- Continuity of Care Document (CCD)
- Diagnostic Imaging Report
- Discharge Summary
- History and Physical
- Operative Note
- Procedure Note
- Progress Note
- Unstructured Document

New as of C-CDA R2.0/R2.1

- Care Plan
- Referral Note
- Transfer Summary



Industry-wide Content Pain Points



Optionality:

More than one way to do things and inconsistent implementations across vendors



Terminology:

Inconsistent terminology usage



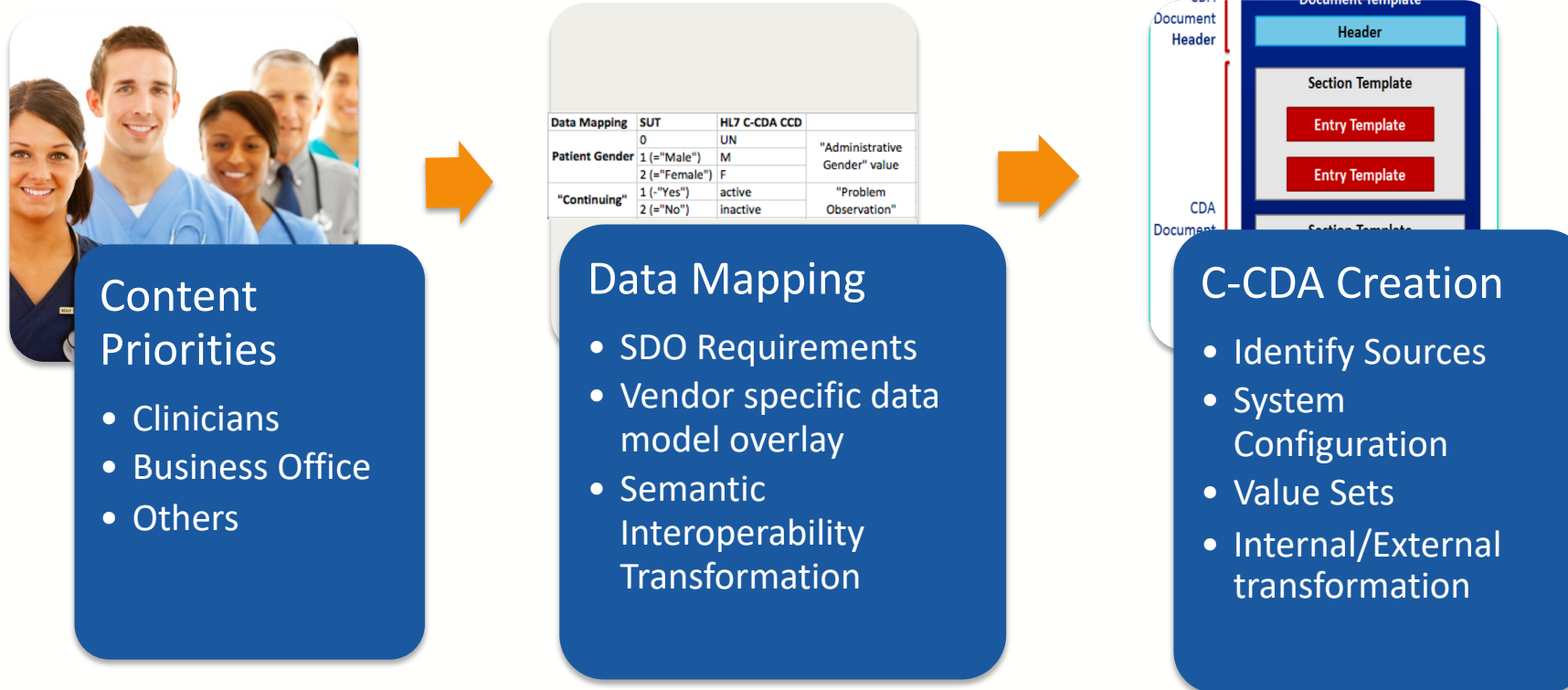
Specification Ambiguity



Complexity:

The C-CDA standard is difficult to understand and consume and is lacking in clearly documented examples

Process for Creating Consistent & Robust HL7 C-CDAs



Enhanced Content Testing Documentation Package

- **Website Page for New Program:**
 - <https://ehealthexchange.org/testing-program/content-testing/>
- **Wiki Page for Current Documentation**
 - <https://ehealthexchange.org/testing-wiki/documentation-for-content-testing-program/>
 - 2018-02-05-Content-Testing-Package.zip
 - eHealth Exchange Content Testing Guide 2018 Version 1.0
 - Content Testing Tools User Guide 2018 Version 2.0
 - RECEIVE Test Files – **VENDORS ONLY – not required for Participants**
 - MU_HITSP_C32C83_4Sections_RobustEntries_NoErrors.xml
 - 170.315_b5_ccds_amb_ccd_r11_sample2_v1.xml
 - 170.315_b5_ccds_amb_ccd_r21_sample1_v1.xml



Validated Product Vendors – Required Testing

- All current Validated vendors will be required to test in 12 months from February 5, 2018
 - Create Test Cases (Using Vendor Supplied Test Data – No PHI please)
 - Receive Test Cases (HITSP C32, R1.1 and R2.1 Documents)
- New Vendors seeking Product Validation will be required to provide one or more content samples as follows:
 - All Vendors will be required to provide samples for testing for each version of HL7 specification they support (HITSP C32, HL7 C-CDA R1.1 or R2.1)
 - All Vendors will be required to provide samples of each document type they support for their customers on an ongoing basis as new documents are added (CCD, Discharge Summary, Progress Note, etc.)

Participant Content Testing Requirements

- All current Participants will be required to test within 12 months from February 5, 2018
 - Create Test Cases (Using Participant specified Test Data – no PHI)
- New Participants seeking to onboard will be required to provide one or more content samples from each Document Source in their community:
 - All Document Sources will be required to provide samples for testing for each version of HL7 specification they support (HITSP C32, C-CDA R1.1 or HL7 C-CDA R2.1)
 - All Document Sources will be required to provide samples of each document type they support in production on an ongoing basis resulting in continuous testing (CCD, Discharge Summary, Progress Note, etc.)

Content Testing Tooling



GAZELLE
eHealth test framework
for interoperability



ART DÉCOR/GAZELLE OBJECTS CHECKER

- Hosted by IHE Services as part of the IHE International Scheme Testing
- Tooling was piloted in April 2015 and is ISO 17025 Compliant for Conformity Assessment
- Covers only the HITSP C32/CCD, HL7 C-CDA CCD R1.1 and R2.1 versions
- Found to report on warnings and errors not found by other testing tooling (<https://gazelle.ihe.net/cda/cda-basic-req.pdf>)
- More information on the tooling can be found in Appendix B of the [eHealth Exchange Content Testing Guide 2018 v1.0](#)

CDA
Document
Header

CDA
Document
Body

Document Template

Header

Section Template

Entry Template

Entry Template

Section Template

Entry Template

Entry Template

Entry Template

Content Testing Survey/Application

- [eHealth Exchange Content Testing Survey / Application](#) form
- **Required** to gain access to tooling
- One form per organization identifying all users to be added for testing
 - Name, email, phone
- Asks for all source systems expected to be tested
- Asks for additional details useful for trading partners to know
 - Some details may be published in the eHealth Exchange Directory in the future

Process to Report Questions, Issue, Defects

- Email one question/issue/defect per email to
 - techsupport@sequoiaproject.org
 - Provide as much information as possible including:
 - Screenshots
 - Testing Permanent Link with Issue
 - Reference details for specification questions/issues

File Name: patient_CCDA_CCD_R2_1_altered.xml
 OID : 1.3.6.1.4.1.12559.11.28.1641
 Schematron : N/A (Version N/A)
 Schematron Validation Result : N/A
 Validation Date : 1/29/18 6:01:04 PM (CET GMT+0100)
 Model Based Validator : HL7 - C-CDAR2.1 - Meaningful Use Stage 3 (Version N/A)
 Model Based Validation Result : **FAILED** [SC](#)
 Permanent link : <https://gazellecontent.sequoiaproject.org/EVSCClient/detailedResult.seam?type=CDA&oid=1.3.6.1.4.1.12559.11.28.1641>

Test	Location	Description
↑ (4/105) ↓	ccda212265	E - 4
	/ClinicalDocument/component/structuredBody/component[6]/section/entry[86]/organizer/component[0]/observation	
		In Vital Sign Observation (V2), in /hl7:observation[hl7:templateId/@root='2.16.840.1.113883.10.20.22.4.27'], the element(s) hl7:value SHALL not have nullFlavor (mandatory) (Item : CONF:1098-7305)[Constrain t...] [Assertion...]

```

<templateId root="2.16.840.1.113883.10.20.22.4.27" extension="2015-08-01"/>
<id extension="00" root="2.16.840.1.113883.3.42.126.100001.19" />
<code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="39156-5" displayName="BMI" />
<text><reference value="#vitals-86"/></text>
<statusCode code="completed" />
<effectiveTime nullFlavor="NI"/>
<value nullFlavor="NI" xsi:type="PQ" />
</observation>
    
```

8. SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:1098-7305).
 - a. This value SHALL contain exactly one [1..1] @unit, which SHALL be selected from ValueSet [UnitsOfMeasureCaseSensitive](#) urn:oid:2.16.840.1.113883.1.11.12839 DYNAMIC (CONF:1098-31579).

I believe the nullFlavor should be allowed for the "value" element since it isn't specifically not allowed. In particular, [CONF:1098-7305](#) requires that the "value" element be present with @xsi:type="PQ", but doesn't state that nullFlavor cannot be used.

Value Sets

<https://vsac.nlm.nih.gov/>

Requires UMLS license/account

Value Set Authority Center
U.S. National Library of Medicine

Welcome | Sign In | Author Registration | Contact Us

Welcome | Search Value Sets | Download | Browse Code Systems | Help

WARNING
VSAC Collaboration Tool will be unavailable from 7:00 A.M. until 1:00 P.M. (ET) on Saturday, 02/03/2018.

The VSAC is a repository and authoring tool for public value sets created by external programs. Value sets are lists of codes and corresponding terms, from NLM-hosted standard clinical vocabularies (such as SNOMED CT®, RxNorm, and Interplan) and interoperable health information exchange. The VSAC does not create value set content. The VSAC also provides a tool for the Centers for Medicare & Medicaid Services (CMS) electronic Clinical Quality Measures (eCQMs). The VSAC is provided by the National Library of Medicine (NLM), in collaboration with the Office of the Assistant Secretary for Health Information Management.

Subscribe to the [VSAC Updates listserv](#) for VSAC announcements.

VSAC Login

Please use your UMLS account to login to VSAC

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Login | Forgot Username | Forgot Password

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Programs

All Value Sets

Explore the entire VSAC repository of published value sets. Search by value set name, object identifier (OID), codes, terms and purpose. Filter by release program, steward, and code systems.

Search

CMS Hybrid Value Sets

Core Clinical Data Elements and Hybrid Measures use a set of core clinical data elements, clinical variables from electronic health records (EHRs), that are routinely collected and can be feasibly extracted for use in risk-adjusted hospital-level hybrid outcome measures. [Learn More](#)

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USA.gov
Last updated: Jan 31, 2018
First published: October 25, 2012
Version: 2.16.3



eHealth Exchange Testing Program Requirements – Proposed Changes

	Baseline Testing - Participants	eHealth Exchange Validated Product	QTS Basic	QTS Intermediate	QTS Advanced
Criteria	Participant successfully completes eHealth Exchange Transport and Security Tests	- Vendor successfully completes eHealth Exchange Product Testing - Participant has decreased testing requirements if using a validated product	- Is an eHealth Exchange Validated System - Uses a Standardized Configuration - Has a minimum of 4 Production Participants completing testing w/no failures - No outstanding technical issues - Recognized as a Federal Fast Track (or equivalent) program partner	Has satisfied ALL QTS Basic requirements AND Successfully submit test reports under QTS Basic for a minimum of 6 months with no issues before being considered by eHealth Exchange staff in consultation with the vendor, CC, and vendor's customers.	Has satisfied all QTS Basic and Intermediate requirements. AND ALL Production Participants utilizing the vendor's approved QTS-Intermediate solution have successfully demonstrated Content Testing Validation, with no errors
Scope	- Transport - Security - Content - PKI Certs	- Transport - Content - PKI Certs	- Transport - Content - PKI Certs	- Content - PKI Certs	PKI Certs
Cost	Participant : \$19,000	- Vendor: \$34,000 - Participant: \$11,000 + content	- Vendor: \$0 - Participant: content	- Vendor: \$0 - Participant: content	- Vendor: \$0 - Participant: \$0
Content Testing is required for all levels <u>EXCEPT</u> QTS Advanced, and will be bundled with Participant fees based on revenue tiers. PKI Cert Testing is required for <u>ALL</u> levels.					



TOOLING DEMO

Sequoia/Gazelle Content Testing Tools
Hosted and Developed in Partnership with IHE Services

<http://www.ihe-services.net/about-us/Why-IHE-Services>

Questions? testing@sequoiaproject.org