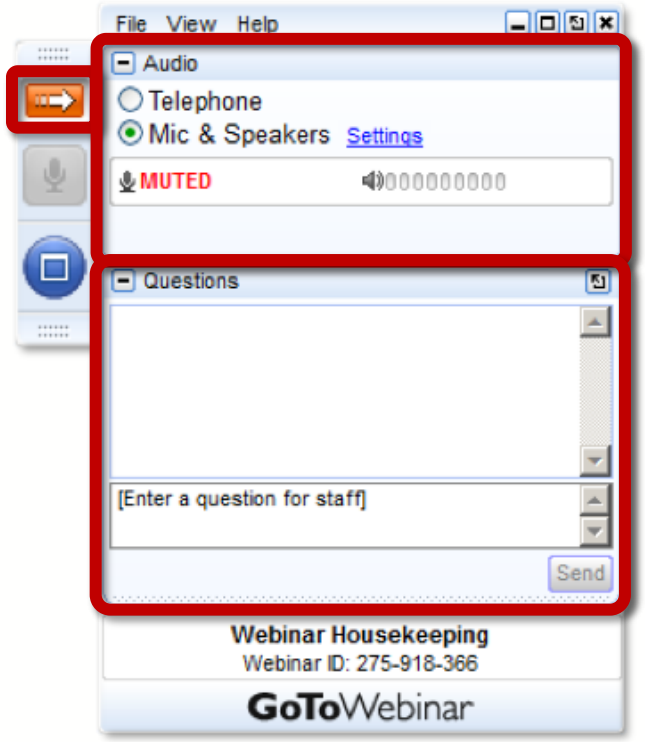
eHealth Exchange™

Enhanced Content Testing Program Launch

Didi Davis, Director of Testing Programs
February 5, 2018

An initiative of the sequoia project®

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
Testing Programs Director

Matt Blackmon
Testing Programs Engineer

Lisa R. Nelson
Subject Matter Expert

Agenda

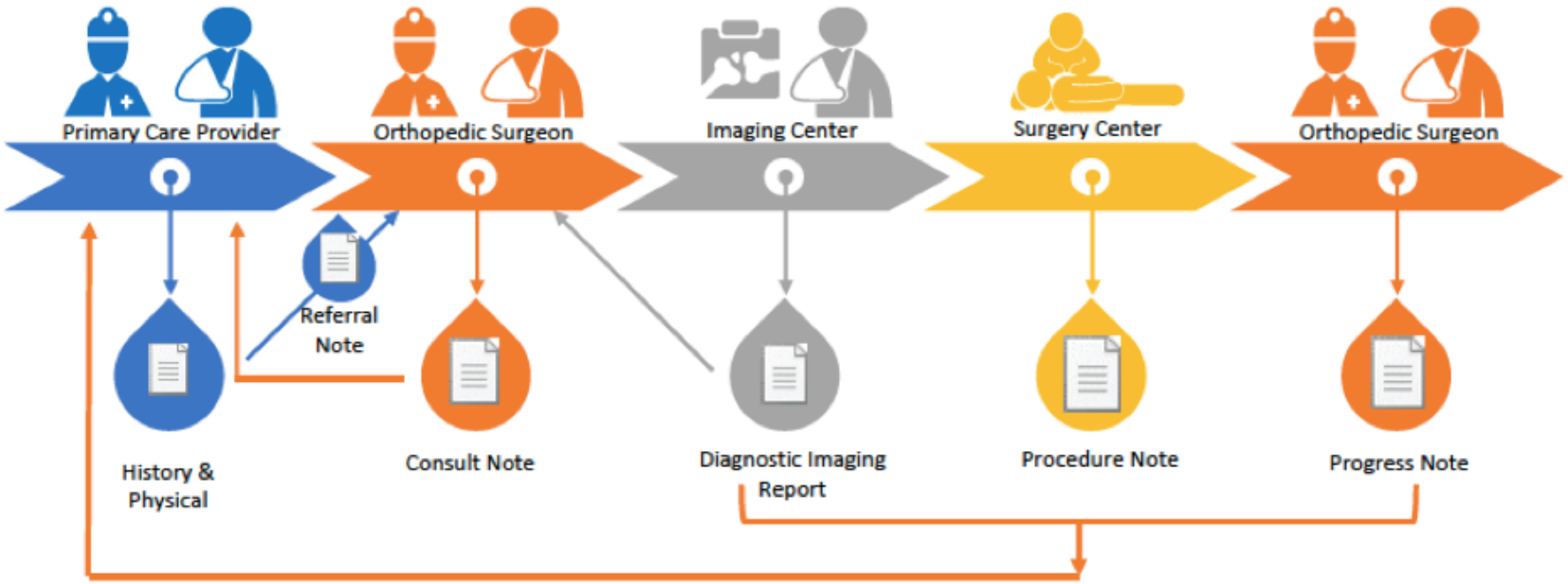
- Background
- New Content Testing Program Details
  - Enhanced Content Testing Documentation Package
  - Content Testing Process
  - Content Testing Tooling
  - Enhanced Content Testing Milestones/Timeline
- Updates for Validation Plan for Qualified Technology Solution
  - QTS to allow for Basic, Intermediate,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

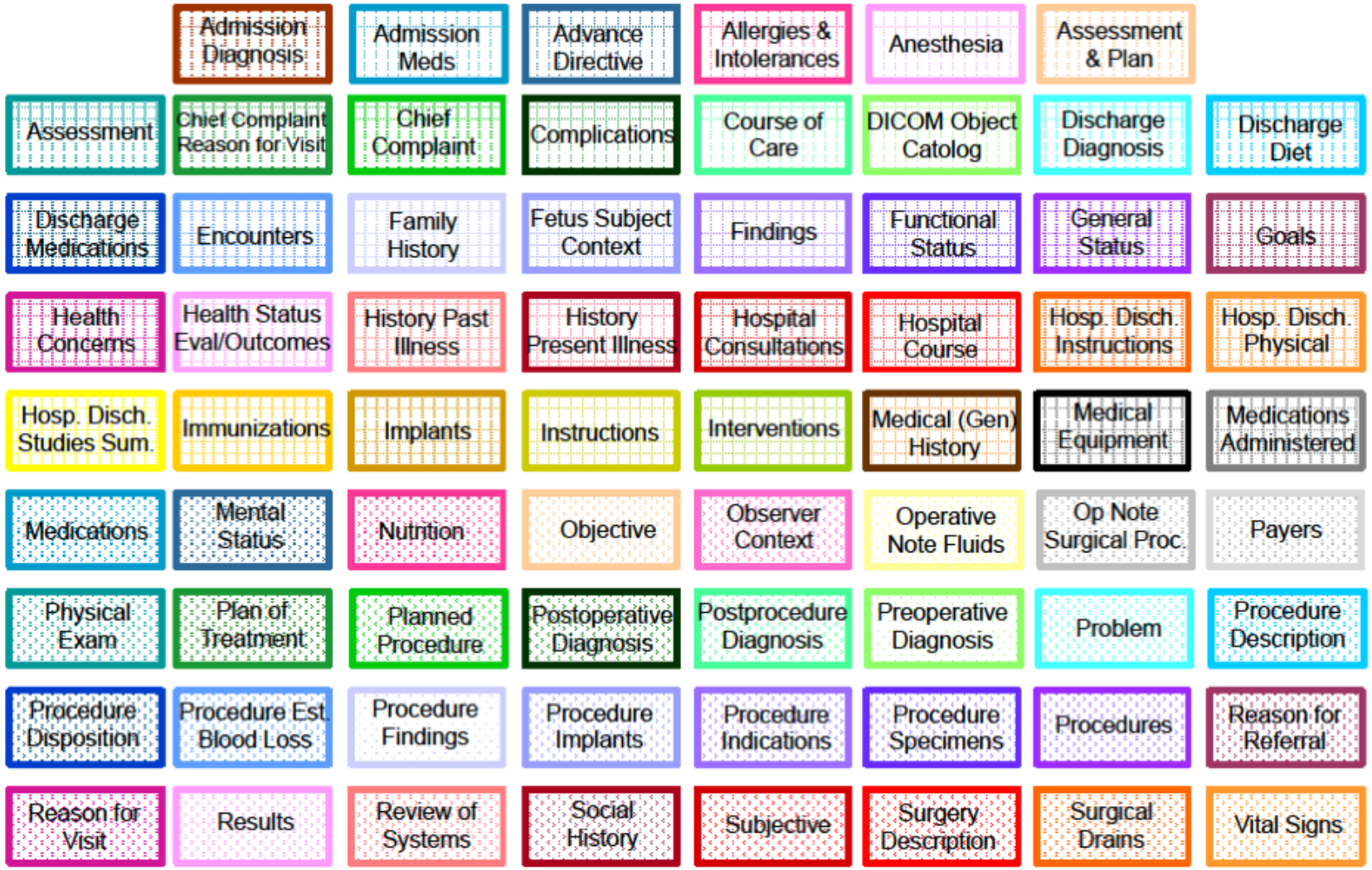
- **Today, most of the clinical data exchanged by systems leverages ONLY the CCD**
- **Many documents are not created by a human but by a machine on demand when queried. Data should be exchanged using appropriate document types.**



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



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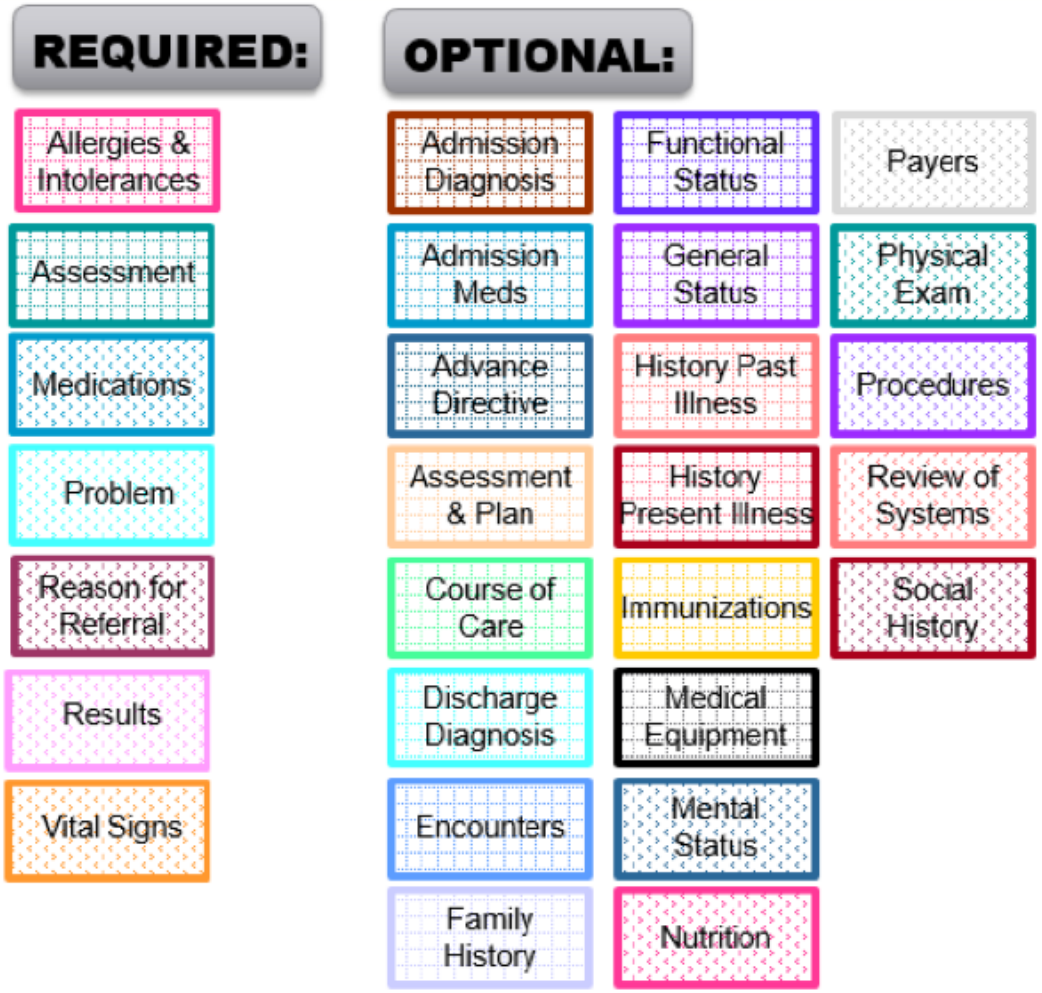
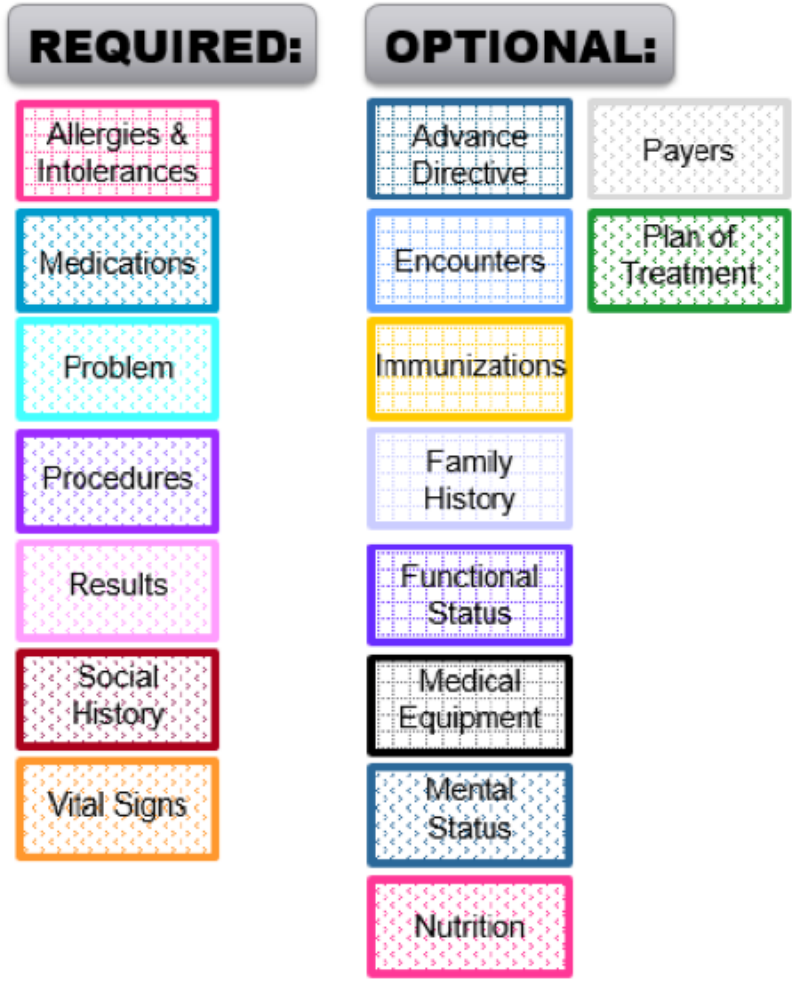
Transfer Summary



CCD



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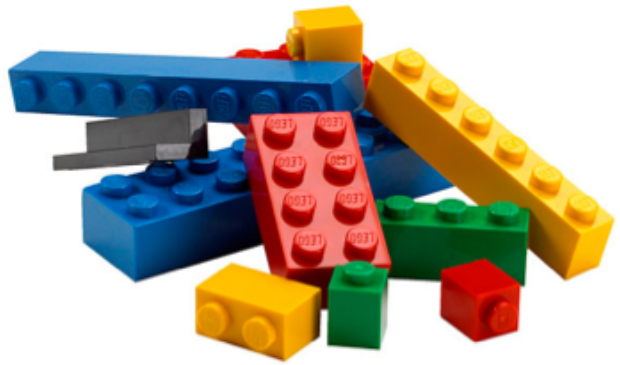
C-CDA R1.1 (9 Types) and R2.1 Document Types (12 Total)

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

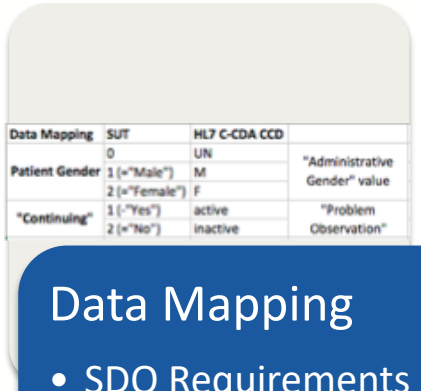
Specification Ambiguity

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

Content Priorities

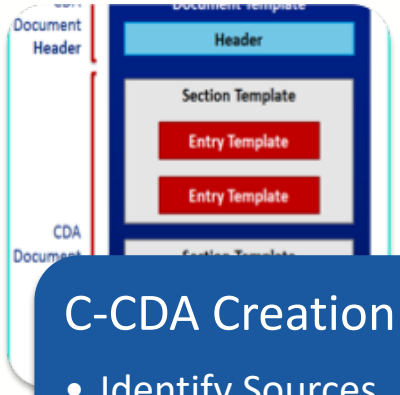
- Clinicians
- Business Office
- Others



Data Mapping	SUT	HL7 C-CDA CCD	
Patient Gender	0	UN	"Administrative Gender" value
	1 (="Male")	M	
	2 (="Female")	F	
"Continuing"	1 (="Yes")	active	"Problem Observation"
	2 (="No")	inactive	

Data Mapping

- SDO Requirements
- Vendor specific data model overlay
- Semantic Interoperability Transformation



C-CDA Creation

- Identify Sources
- System Configuration
- Value Sets
- Internal/External transformation

Enhanced Content Testing Documentation Package

- **Website Page for New Program:**
  - http://sequoiaproject.org/ehealth-exchange/testing-overview/content-testing/
- **Wiki Page for Current Documentation**
  - http://ehealth-exchange-testing.wikispaces.com/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 1.0
    - 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

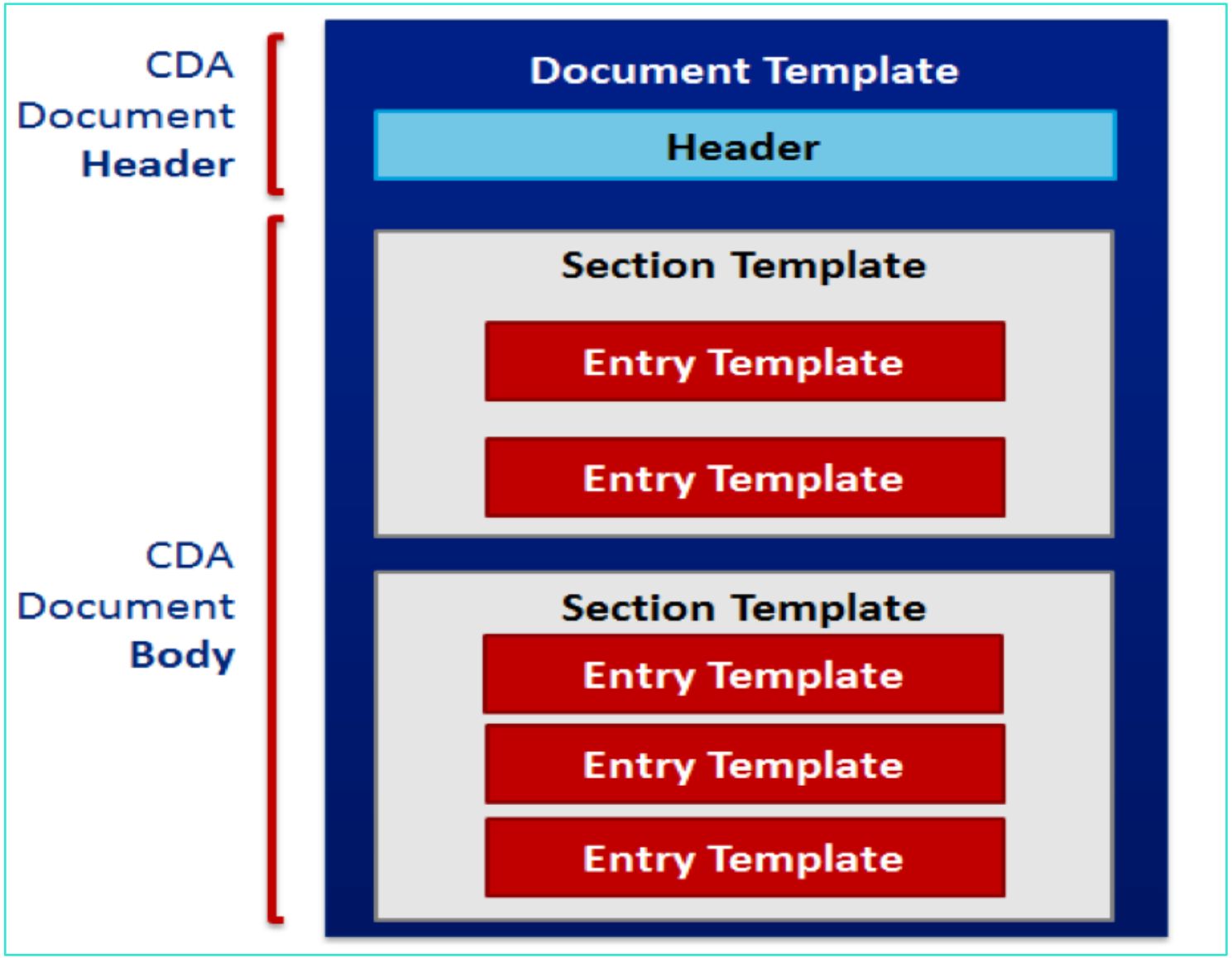
- All current Participants will be required to test within 12 months from February 5, 2018
  - Create Test Cases (Using Participant specified Test Data – no PHI)
- New Participants seeking to onboard will be required to provide one or more content samples from each Document Source in their community:
  - 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

IHE | 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



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
  - testing@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-CDA R2.1 - Meaningful Use Stage 3 (Version N/A)
Model Based Validation Result : FAILED SC
Permanent link : https://gazellecontent.sequoiaproject.org/EVSClient/detailedResult.seam?type=CDA&oid=1.3.6.1.4.1.12559

(4/105)	Test	ccda212265	E - 4
	Location	/ClinicalDocument/component/structuredBody/component[6]/section/entry[86]/organizer/component[0]/observation	
	Description	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)[Constraint...] [Assertion...]	

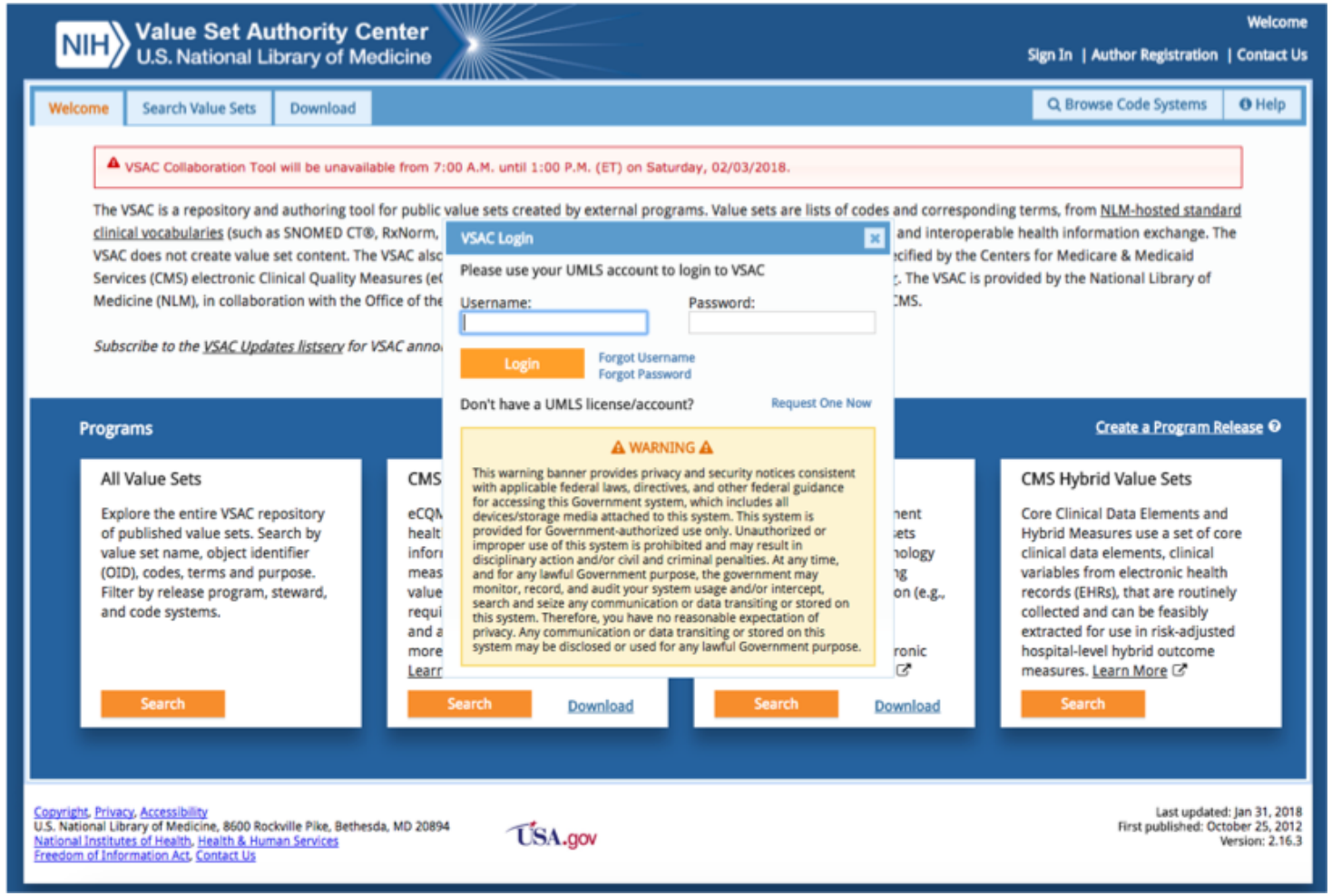
```
<templateId root="2.16.840.1.113883.10.20.22.4.27" extension="2015-08-01"/>
<id extension="00" root="2.16.840.1.113883.3.42.126.100001.19" />
<code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="39156-5" displayName="BMI" />
<text><reference value="#vitals-86"/></text>
<statusCode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

</observation>
```

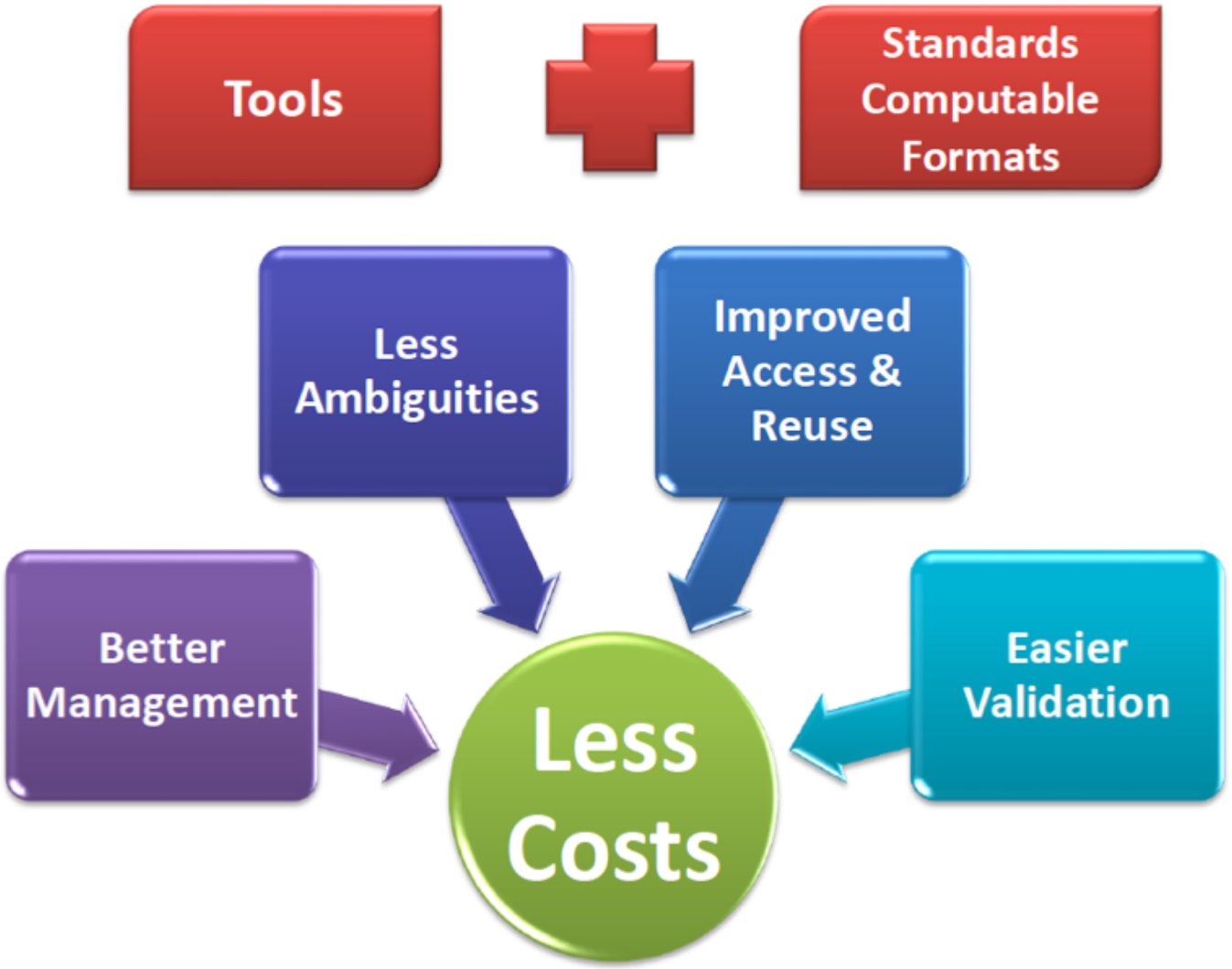
8. **SHALL** contain exactly one [1..1] `value` with @xsi:type="PQ" (CONF:1098-7305).
    a. This value **SHALL** contain exactly one [1..1] `@unit`, which **SHALL** be selected from ValueSet `UnitsOfMeasureCaseSensitive` `urn:oid:2.16.840.1.113883.1.11.12839` **DYNAMIC** (CONF:1098-31579).

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





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 EXCEPT QTS Advanced, and will be bundled with Participant fees based on revenue tiers. PKI Cert Testing is required for ALL levels.

Questions? testing@sequoiaproject.org

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