Department of Veterans Affairs
Veteran Health Administration
Knowledge Based Systems

Informatics Architecture Support Services

FHIR Profiles and Consolidated CDA Templates: Data-Modeling Issues With Implications for Patient Safety

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Outline

- Interoperability standards and patient safety

- FHIR US Core Implementation Guide
  - Under-specification
  - Negation issues
  - Modifying elements
  - "Must-support" elements
  - Terminology issues

- Consolidated CDA Implementation Guide
  - Unnecessary complexity
  - Missing "required" values
  - Negation issues
  - Terminology issues

Interoperability standards and patient safety

- National standards are increasingly used to access and exchange clinically important patient data
  - Summary documents (e.g., HL7 CDA)
  - Application programming interfaces (e.g., HL7 FHIR)
- Automated decision support is increasingly reliant on structured data that are accessed or exchanged via these standards
  - E.g., CDA documents used to drive medication reconciliation upon admission to or discharge from hospital
  - E.g., FHIR APIs used to provide EHR data to 3rd-party applications that optimize or review care in inpatient or outpatient settings
- Loss or misinterpretation of clinical data by recipient systems can adversely impact clinical care and, therefore, patient safety
  - Hence, standard data models must fully, clearly, and unambiguously represent the clinical meaning of patient data

FHIR Resources and FHIR Profiles

- **FHIR Resources**

Name	Flags	Card.	Type	Description & Constraints
Observation	I		DomainResource	Measurements and simple assertions + If code is the same as a component code then the value element associated with the code SHALL NOT be present + dataAbsentReason SHALL only be present if Observation.value[x] is not present Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier	Σ	0..*	Identifier	Business Identifier for observation
basedOn	Σ	0..*	Reference(CarePlan | DeviceRequest | ImmunizationRecommendation | MedicationRequest | NutritionOrder | ProcedureRequest | ReferralRequest)	Fulfills plan, proposal or order
status	?! Σ	1..1	code	registered | preliminary | final | amended + ObservationStatus (Required)
category		0..*	CodeableConcept	Classification of type of observation Observation Category Codes (Preferred)
code	Σ	1..1	CodeableConcept	Type of observation (code / type) LOINC Codes (Example)
subject	Σ	0..1	Reference(Patient | Group | Device | Location)	Who and/or what this is about
context		0..1	Reference(Encounter | EpisodeOfCare)	Healthcare event during which this observation is made
effective[x]	Σ	0..1		Clinically relevant time/time-period for observation
effectiveDateTime			dateTime	
effectivePeriod			Period	
issued	Σ	0..1	instant	Date/Time this was made available
performer	Σ	0..*	Reference(Practitioner | Organization | Patient | RelatedPerson)	Who is responsible for the observation
value[x]	Σ I	0..1		Actual result

Profiling FHIR Resources

Text Summary | **Differential Table** | **Snapshot Table** | **All**

Name	Flags	Card.	Type	Description & Constraints
📁 Observation	I	0..*		US Core Result Observation us-core-2: If there is no component or related element then either a value[x] or a data absent reason must be present
status	S	1..1	code	**Binding:** ObservationStatus (required)
category	S I	1..*	CodeableConcept	us-core-5: Must have a category of 'laboratory' and a code system 'http://hl7.org/fhir/observation-category'
code	S	1..1	CodeableConcept	Laboratory Test Name **Binding:** LOINC Codes (extensible)
subject	S	1..1	Reference(US Core Patient Profile)	
effective[x]	S I	0..1	dateTime, Period	us-core-1: Datetime must be at least to day.
value[x]	S I	0..1	Quantity, CodeableConcept, string, boolean, Range, Ratio, SampledData, Attachment, time, dateTime, Period	Result Value us-core-4: SHOULD use Snomed CT for coded Results us-core-3: SHALL use UCUM for coded quantity units.

Result Observation
("U.S. Core" Resource <u>Profile</u>)

Name				
📁 Observa...				
identi...				ObservationStatus (Required)
based...				
statu...				
category		0..*	CodeableConcept	Classification of type of observation Observation Category Codes (Preferred)
code	Σ	1..1	CodeableConcept	Type of observation (code / type) LOINC Codes (Example)
subject	Σ	0..1	Reference(Patient | Group | Device | Location)	Who and/or what this is about
context		0..1	Reference(Encounter | EpisodeOfCare)	Healthcare event during which this observation is made
effective[x]	Σ	0..1		Clinically relevant time/time-period for observation
effectiveDateTime			dateTime	
effectivePeriod			Period	
issued	Σ	0..1	instant	Date/Time this was made available
performer	Σ	0..*	Reference(Practitioner | Organization | Patient | RelatedPerson)	Who is responsible for the observation
value[x]	Σ I	0..1		Actual result
bodySite		0..1	CodeableConcept	Observed body part SNOMED CT Body Structures (Example)
method		0..1	CodeableConcept	How it was done Observation Methods (Example)
specimen		0..1	Reference(Specimen)	Specimen used for this observation
device		0..1	Reference(Device | DeviceMetric)	(Measurement) Device
referenceRange	I	0..*	BackboneElement	Provides guide for interpretation

Observation
(HL7 Core Resource)

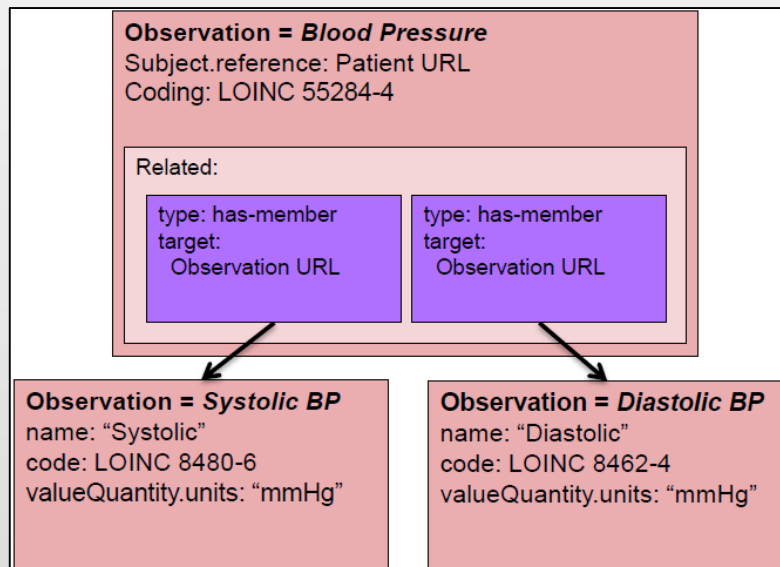# FHIR US Core – Underspecification

- Existing FHIR profiles still allow too much variability in the way that clinical data may be specified

- Example: Blood Pressure measurement (systolic/diastolic) using Observation and/or Diagnostic Report resources

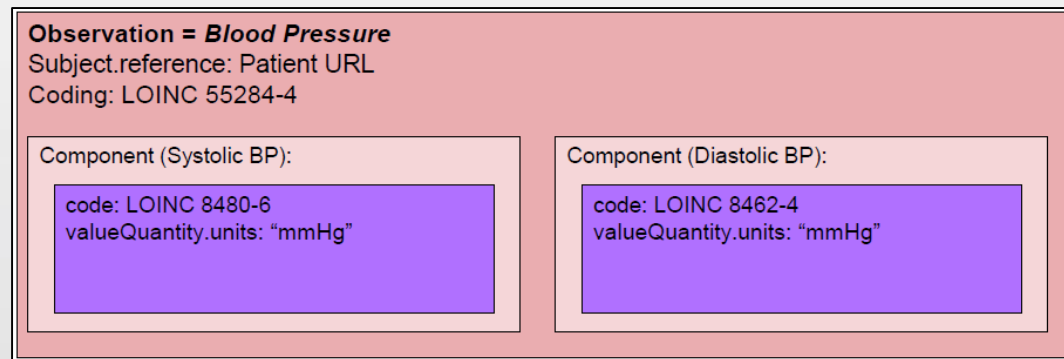| Name	Flags	Card.	Type
Observation	I		DomainResource
code	Σ	1..1	CodeableConcept
subject	Σ	0..1	Reference(Patient | Group | Device | Location)
value[x]	Σ I	0..1	
related	Σ	0..*	BackboneElement
type		0..1	code
target		1..1	Reference(Observation | QuestionnaireResponse | Sequence)
component	Σ	0..*	BackboneElement
code	Σ	1..1	CodeableConcept
value[x]	Σ	0..1	

FHIR US Core – Underspecification

- Existing FHIR profiles still allow too much variability in the way that clinical data may be specified

- Example: Blood Pressure measurement (systolic/diastolic) using <u>Observation</u> and/or <u>Diagnostic Report</u> resources

Observation = *Blood Pressure*
Subject.reference: Patient URL
Coding: LOINC 55284-4

Related:

| type: has-member
target:
  Observation URL | type: has-member
target:
  Observation URL |

Observation = *Systolic BP*
name: "Systolic"
code: LOINC 8480-6
valueQuantity.units: "mmHg"

Observation = *Diastolic BP*
name: "Diastolic"
code: LOINC 8462-4
valueQuantity.units: "mmHg"

FHIR US Core – Underspecification

- Existing FHIR profiles still allow too much variability in the way that clinical data may be specified

- Example: Blood Pressure measurement (systolic/diastolic) using Observation and/or Diagnostic Report resources

Name	Flags	Card.	Type
Observation	I		DomainResource
code	Σ	1..1	CodeableConcept
subject	Σ	0..1	Reference(Patient | Group | Device | Location)
value[x]	Σ I	0..1	
related	Σ	0..*	BackboneElement
type		0..1	code
target		1..1	Reference(Observation | QuestionnaireResponse | Sequence)
component	Σ	0..*	BackboneElement
code	Σ	1..1	CodeableConcept
value[x]	Σ	0..1	

- Existing FHIR profiles still allow too much variability in the way that clinical data may be specified

- Example: Blood Pressure measurement (systolic/diastolic) using <u>Observation</u> and/or <u>Diagnostic Report</u> resources
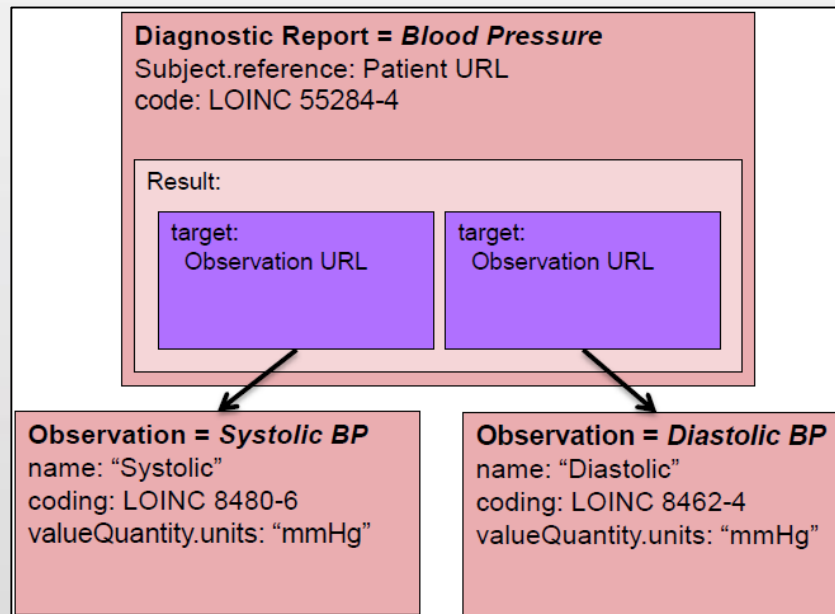
Observation = *Blood Pressure*
Subject.reference: Patient URL
Coding: LOINC 55284-4

Component (Systolic BP):

code: LOINC 8480-6
valueQuantity.units: "mmHg"

Component (Diastolic BP):

code: LOINC 8462-4
valueQuantity.units: "mmHg"

FHIR US Core – Underspecification

- Existing FHIR profiles still allow too much variability in the way that clinical data may be specified

- Example: Blood Pressure measurement (systolic/diastolic) using <u>Observation</u> and/or <u>Diagnostic Report</u> resources

Name	Flags	Card.	Type
Observation	I		DomainResource
code	Σ	1..1	CodeableConcept
subject	Σ	0..1	Reference(Patient | Group | Device | Location)
value[x]	Σ I	0..1	
related	Σ	0..*	BackboneElement
type		0..1	code
target		1..1	Reference(Observation | QuestionnaireResponse | Sequence)
component	Σ	0..*	BackboneElement
code	Σ	1..1	CodeableConcept
value[x]	Σ	0..1	

Name	Flags	Card.	Type
DiagnosticReport			DomainResource
code	Σ	1..1	CodeableConcept
subject	Σ	0..1	Reference(Patient | Group | Device | Location)
result		0..*	Reference(Observation)

- Existing FHIR profiles still allow too much variability in the way that clinical data may be specified

- Example: Blood Pressure measurement (systolic/diastolic) using <u>Observation</u> and/or <u>Diagnostic Report</u> resources

FHIR US Core – Underspecification

- Existing FHIR profiles may lack needed clinical detail, necessitating *ad hoc* extension elements

- Example: Patient posture for Blood Pressure measurement

Name	Flags	Card.	Type
Observation	I		DomainResource
code	Σ	1..1	CodeableConcept
subject	Σ	0..1	Reference(Patient | Group | Device | Location)
value[x]	Σ I	0..1	
related	Σ	0..*	BackboneElement
type		0..1	code
target		1..1	Reference(Observation | QuestionnaireResponse | Sequence)
component	Σ	0..*	BackboneElement
code	Σ	1..1	CodeableConcept
value[x]	Σ	0..1	

FHIR US Core – Underspecification

- Existing FHIR profiles may lack needed clinical detail, necessitating *ad hoc* extension elements

- Example: Patient posture for Blood Pressure measurement

```json
{
 "resourceType" : "Observation",
 "id" : "blood-pressure",
 "meta" : {  "profile" : [ "http://hl7.org/fhir/StructureDefinition/vitalsigns" ] },
 ...lines omitted...
 "effectiveDateTime" : "1999-07-02",
 "extension" : [
   {
    "url" : "http://myhospital.org/fhir/StructureDefinition/bp-position",
    "valueCoding" : {
     "system" : "urn:oid:2.16.840.1.18760.6.238",
     "code" : "C4877",
     "display" : "Sitting"
    }
   }
 ]
 "component" : [
  {
   "code" : {
    "coding" : [
     {  "system" : "http://loinc.org",  "code" : "8480-6",  "display" : "Systolic blood pressure"  }
    ],
    "text" : "Systolic blood pressure"
   },
   "valueQuantity" : { "value" : 109, "unit" : "mmHg", "system" : "http://unitsofmeasure.org", "code" : "mm[Hg]" }
  },
  ...lines omitted...
 ]
}
```

FHIR US Core – Negation Issues

- Multiple ways to negate the same clinical statement

Name	Flags	Card.	Type	Description & Constraints
Condition	I		DomainResource	Detailed information about conditions, problems or diagnoses + If condition is abated, then clinicalStatus must be either inactive, resolved, or remission + Condition.clinicalStatus SHALL be present if verificationStatus is not entered-in-error Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier	Σ	0..*	Identifier	External Ids for this condition
clinicalStatus	?! Σ I	0..1	code	active | recurrence | inactive | remission | resolved Condition Clinical Status Codes (Required)
verificationStatus	?! Σ I	0..1	code	provisional | differential | confirmed | refuted | entered-in-error | unknown ConditionVerificationStatus (Required)
category		0..*	CodeableConcept	problem-list-item | encounter-diagnosis Condition Category Codes (Example)
severity		0..1	CodeableConcept	Subjective severity of condition Condition/Diagnosis Severity (Preferred)
code	Σ	0..1	CodeableConcept	Identification of the condition, problem or diagnosis e.g., "Rash" Condition/Problem/Diagnosis Codes (Example)
bodySite	Σ	0..*	CodeableConcept	Anatomical location, if relevant SNOMED CT Body Structures (Example)
subject	Σ	1..1	Reference(Patient | Group)	Who has the condition?
context	Σ	0..1	Reference(Encounter | EpisodeOfCare)	Encounter or episode when condition first asserted
onset[x]	Σ	0..1		Estimated or actual date, date-time, or age

FHIR US Core – Negation Issues

- Multiple ways to negate the same clinical statement
    1. clinicalStatus
    2. verificationStatus
    3. Code
        - SNOMED-CT code of the type "Situation With Explicit Context", which itself can denote the absence or negation of a specific clinical condition
            EXAMPLE: "No cardiovascular symptom" [SCT 162001003]
        OR
        - SNOMED-CT code "No current problems or disability" [SCT 160245001]

- Undefined scope of negation

Name	Flags	Card.	Type	Description & Constraints
Condition	I		DomainResource	Detailed information about conditions, problems or diagnoses + If condition is abated, then clinicalStatus must be either inactive, resolved, or remission + Condition.clinicalStatus SHALL be present if verificationStatus is not entered-in-error Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier	Σ	0..*	Identifier	External Ids for this condition
clinicalStatus	?! Σ I	0..1	code	active | recurrence | inactive | remission | resolved Condition Clinical Status Codes (Required)
verificationStatus	?! Σ I	0..1	code	provisional | differential | confirmed | refuted | entered-in-error | unknown ConditionVerificationStatus (Required)
category		0..*	CodeableConcept	problem-list-item | encounter-diagnosis Condition Category Codes (Example)
severity		0..1	CodeableConcept	Subjective severity of condition Condition/Diagnosis Severity (Preferred)
code	Σ	0..1	CodeableConcept	Identification of the condition, problem or diagnosis Condition/Problem/Diagnosis Codes (Example)
bodySite	Σ	0..*	CodeableConcept	Anatomical location, if relevant SNOMED CT Body Structures (Example)
subject	Σ	1..1	Reference(Patient | Group)	Who has the condition?
context	Σ	0..1	Reference(Encounter | EpisodeOfCare)	Encounter or episode when condition first asserted
onset[x]	Σ	0..1		Estimated or actual date, date-time, or age

e.g., "Rash"

e.g., "Left arm"

e.g., "April 10, 2018"

- Absence of negation elements for certain resource profiles
  - Procedure*
    - E.g., "No past cardiac catheterization"
  - FamilyMemberHistory*
    - E.g., "No history of cancer in mother or father"

* Unless a discrete code exists representing the negated concept, e.g. a SNOMED "situation with explicit context" code

FHIR US Core – Modifying Elements

Name	Flags	Card.	Type	Description & Constraints
Condition	I		DomainResource	Detailed information about conditions, problems or diagnoses + If condition is abated, then clinicalStatus must be either inactive, resolved, or remission + Condition.clinicalStatus SHALL be present if verificationStatus is not entered-in-error Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier	Σ	0..*	Identifier	External Ids for this condition
clinicalStatus	?! Σ I	0..1	code	active | recurrence | inactive | remission | resolved Condition Clinical Status Codes (Required)
verificationStatus	?! Σ I	0..1	code	provisional | differential | confirmed | refuted | entered-in-error | unknown ConditionVerificationStatus (Required)
category		0..*	CodeableConcept	problem-list-item | encounter-diagnosis Condition Category Codes (Example)
severity		0..1	CodeableConcept	Subjective severity of condition Condition/Diagnosis Severity (Preferred)
code	Σ	0..1	CodeableConcept	Identification of the condition, problem or diagnosis Condition/Problem/Diagnosis Codes (Example)	e.g., "Rash"
bodySite	Σ	0..*	CodeableConcept	Anatomical location, if relevant SNOMED CT Body Structures (Example)	e.g., "Left arm"
subject	Σ	1..1	Reference(Patient | Group)	Who has the condition?
context	Σ	0..1	Reference(Encounter | EpisodeOfCare)	Encounter or episode when condition first asserted
onset[x]	Σ	0..1		Estimated or actual date, date-time, or age	e.g., "April 10, 2018"

HL7 Specification: An element is labeled "Is-Modifier = true" if the value it contains may change the interpretation of the element that contains it (including if the element is the resource as a whole)... When an element is labeled as Is-Modifier...it is not safe for implementations to ignore it.

- Potential for misinterpretation by senders or recipients

Name	Flags	Card.	Type	Description & Constraints
Condition	I		DomainResource	Detailed information about conditions, problems or diagnoses + If condition is abated, then clinicalStatus must be either inactive, resolved, or remission + Condition.clinicalStatus SHALL be present if verificationStatus is not entered-in-error Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier	Σ	0..*	Identifier	External Ids for this condition
clinicalStatus	?! Σ I	0..1	code	active | recurrence | inactive | remission | resolved Condition Clinical Status Codes (Required)
verificationStatus	?! Σ I	0..1	code	provisional | differential | confirmed | refuted | entered-in-error | unknown ConditionVerificationStatus (Required)
category		0..*	CodeableConcept	problem-list-item | encounter-diagnosis Condition Category Codes (Example)
severity		0..1	CodeableConcept	Subjective severity of condition Condition/Diagnosis Severity (Preferred)
code	Σ	0..1	CodeableConcept	Identification of the condition, problem or diagnosis *e.g., "Depression"* Condition/Problem/Diagnosis Codes (Example)
bodySite	Σ	0..*	CodeableConcept	Anatomical location, if relevant SNOMED CT Body Structures (Example)
subject	Σ	1..1	Reference(Patient | Group)	Who has the condition?
context	Σ	0..1	Reference(Encounter | EpisodeOfCare)	Encounter or episode when condition first asserted
onset[x]	Σ	0..1		Estimated or actual date, date-time, or age

"Refuted" (HL7 specification): "Has been ruled out by diagnostic and clinical evidence"

"Refuted" (Clinical vernacular): "has been characterized by the patient as not present" [arguably]

- Modifying <u>Extension</u> elements may not be recognized by receiving systems

```
{
  "resourceType" : "Procedure",
  "id" : "no cardiac cath",
  "meta" : {
    "profile" : [
      "http://hl7.org/fhir/us/core/StructureDefinition/us-core-procedure"
    ]
  },
  ...lines omitted...
  "modifierExtension" : [
    {
      "url" : "http://myhospital/fhir/StructureDefinition/procNegation",
      "valueBoolean" : {
        "system" : "urn:oid:2.16.840.1.18760.6.238",
        "code" : "F",
        "display" : "false"
      }
    }
  ]
  "code" : {
    "coding" : [
      {
        "system" : "http://snomed.info/sct",
        "code" : "41976001",
        "display" : "Cardiac catheterization"
      },
    ],
  },
  ...lines omitted...
  ]
}
```

- The Must Support elements in FHIR US Core profiles are not defined

Name	Flags	Card.	Type	Description & Constraints
📁 Condition	I	0..*		US Core Condition Profile
				us-core-1: A code in Condition.category SHOULD be from US Core Condition Category Codes value set.
id	Î£	0..1	id	Logical id of this artifact
meta	Î£	0..1	Meta	Metadata about the resource
clinicalStatus	?! S Î£ I	0..1	code	active | recurrence | inactive | remission | resolved
				Binding: Condition Clinical Status Codes (required)
verificationStatus	?! S Î£ I	1..1	code	provisional | differential | confirmed | refuted | entered-in-error | unknown
				Binding: ConditionVerificationStatus (required)
category	S	1..*	CodeableConcept	problem-list-item | encounter-diagnosis
				Binding: US Core Condition Category Codes (preferred)
severity		0..1	CodeableConcept	Subjective severity of condition
				Binding: Condition/Diagnosis Severity (preferred)
code	S Î£	1..1	CodeableConcept	Identification of the condition, problem or diagnosis
				Binding: Problem Value Set (extensible)
bodySite	Î£	0..*	CodeableConcept	Anatomical location, if relevant
				Binding: SNOMED CT Body Structures (example)
subject	S Î£	1..1	Reference(US Core Patient Profile)	Who has the condition?
context	Î£	0..1	Reference(Encounter), Reference(EpisodeOfCare)	Encounter or episode when condition first asserted
onset[x]	Î£	0..1	dateTime, Age, Period, Range, string	Estimated or actual date, date-time, or age

The meaning of "support" is not defined by the base FHIR specification, but can be set to true in a profile. When a profile does this, it SHALL also make clear exactly what kind of "support" is required.

FHIR US Core – "Must Support" Elements

- The Must Support elements in FHIR US Core profiles are not defined

The meaning of "support" is not defined by the base FHIR specification, but can be set to true in a profile. When a profile does this, it SHALL also make clear exactly what kind of "support" is required. Examples might include:

- The system must be able to store and retrieve the element
- The system must display the element to the user and/or allow the user to capture the element via the UI
- The element must appear in an output report
- The element must be taken into account when performing decision support, calculations or other processing
- etc.

But, no such specification for "must-support" data elements is provided in the FHIR US Core implementation guide.

- ## Overlapping Coding Systems/Value Sets

  - *AllergyIntolerance* resource profile allows drugs to be encoded using <u>either RxNorm, SNOMED-CT, or NDF-RT</u> (with prioritization of NDF-RT for drug classes, and prioritization of RxNorm when an RxNorm code is applicable).   Sending systems may not always be aware of this "fine print" in the specifications and may transmit values from improper coding systems. Receiving system that expects senders to scrupulously apply the prioritization rules might not recognize the code, resulting in a missed patient drug allergy. <u>Such an error would not be caught by a FHIR validation engine.</u>

  - Condition resource profile allows patient problems to be represented using codes from either the SNOMED-CT "Clinical Finding" hierarchy or the SNOMED-CT "Situation-With-Explicit-Context" hierarchy (i.e., both hierarchies are included in the specified value set).

    - Finding: "Dizziness (finding)"
      [SCTID: 404640003]

    - Situation-with-Explicit-Context: "Dizziness present (situation)"
      [SCTID: 162260006]

- Optional Coding Systems/Value Sets
  - *Observation* resource profile specifies that implementers "<u>SHOULD</u>" use only codes from SNOMED-CT for coded results when populating the "value" data element.
    - <u>SHOULD</u>: "Best practice or recommendation to be considered by implementers within the context of their particular implementation"
    - <u>SHALL</u>: "An absolute requirement"
  - *Condition* resource profile specifies that implementers must use codes from a designated "Problem" value set when populating the "code" data element, but this terminology constraint is designated as "<u>extensible</u>".
    - FHIR specification: "The code populating this data element SHALL be from the specified value [SNOMED-CT] set <u>if any of the codes within the value set can apply to the concept being communicated. If the value set does not cover the concept (based on human review), alternate codes (or text) may be included instead.</u>"
    - ICD-10: "Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of inguinal region and lower limb" [ICD-10 C81.05]
    - SNOMED-CT: "Hodgkin lymphoma, nodular lymphocyte predominance" [SCTID 70600005])

Clinical Document Architecture and CDA Templates

- Clinical Document Architecture (CDA)
  - Standard formalism for representing clinical data in XML documents
  - Based on HL7 v3 Reference Information Model (RIM)
    - Acts, Observations, Moods, Data Types, Vocabulary Domains, …
  - Very general and underconstrained
- CDA Templates
  - Mechanism to further constrain CDA data model
    - Structural constraints (required/allowed data elements and sub-elements)
    - Value constraints (data types, coding systems, value sets)
  - Specify <u>document types</u>
    - E.g., Discharge summary, referral note, CCD
  - Specify <u>sections</u> in document types
    - E.g., Problem list, medication list, immunizations, family history, plan of care
  - Specify <u>entries</u> in sections (e.g., Immunization activity, problem observation)

CDA Templates

Table 179: Problem Section (entries required) (V3) Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
code	1..1	SHALL		1198-15409	
@code	1..1	SHALL		1198-15410	11450-4
@codeSystem	1..1	SHALL		1198-31142	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
title	1..1	SHALL		1198-9181	
text	1..1	SHALL		1198-9182	
entry	1..*	SHALL		1198-9183	
act	1..1	SHALL		1198-15506	Problem Concern Act (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.3:2015-08-01

Consolidated CDA Implementation Guide

- A large set of CDA document, section, and entry templates that reference each other

  - Based on multiple HITSP implementation guides developed in 2000's
  - Consolidated by HL7 into a single specification/documentation package in 2012
  - Designed to support CMS Meaningful Use program
  - Version 1.1 (2012) and version 2.1 (2015)

- C-CDA templates improve interoperability relative to "base" CDA and HITSP implementation guides

- BUT, certain features of C-CDA templates create potential patient-safety concerns

  - Analysis based on C-CDA Release 2.1

Consolidated CDA – Unnecessary Complexity

- Allergenic Substance in *Allergy Intolerance Observation* template

```
<observation classCode="OBS" moodCode="EVN">    <!— Allergy – Intolerance Observation  template -->
  ...lines omitted...
  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low nullFlavor="UNK"/>
  </effectiveTime>
  <value xsi:type="CD" code="419199007" displayName="Allergy to substance" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
  <participant typeCode="CSM">
    <participantRole classCode="MANU">
      <playingEntity classCode="MMAT">
        <code code="2670" displayName="Codeine" codeSystem="2.16.840.1.113883.6.88" codeSystemName="RxNorm"/>
      </playingEntity>
    </participantRole>
  </participant>
</observation>
```

- statusCode values of problem in *Problem Section* template

```xml
<section>   <!-- Problem Section template -->
   ...lines omitted...
   <act classCode="ACT" moodCode="EVN">   <!-- Problem Concern Act  template -->
       ...lines omitted...
     <statusCode code="active"/>   <!-- Means this is of ongoing concern to the provider -->
     <effectiveTime>
        <low value="200704141515-0800"/>   <!-- Concern was documented on Apr 14, 2007 -->
     </effectiveTime>
     <entryRelationship typeCode="SUBJ">
       <observation classCode="OBS" moodCode="EVN">   <!--  Problem Observation  template-->
          ...lines omitted...
         <code code="64572001" displayName="Condition" codeSystemName="SNOMED-CT" codeSystem="2.16.840.1.113883.6.96"/>
         <statusCode code="completed"/>   <!-- This statusCode reflects the status of the observation itself -->
         <effectiveTime>
           <low value="20070414"/>   <!-- The low value reflects the date of onset -->
                         <!-- Absence of <high> element means the condition is not resolved -->
         </effectiveTime>
         <value xsi:type="CD" code="29857009" codeSystem="2.16.840.1.113883.6.96" displayName="Chest pain"/>
       </observation>
     </entryRelationship>
   </act>
<section>
```

```
Problem Section
   Problem Concern Act 1
      Problem Observation 1
      Problem Observation 2
      ...
   Problem Concern Act 2
      Problem Observation 3
      ...
```

Is the chest pain currently active or resolved?

Consolidated CDA – Unnecessary Complexity

- statusCode values of problem in *Problem Section* template

```xml
<section>  <!-- Problem template -->
   ...lines omitted...
  <act classCode="ACT" moodCode="EVN">    <!-- Problem Concern Act  template -->
        lines omitted
      <statusCode code="active"/>   <!-- Means this is of ongoing concern to the provider -->
      <effectiveTime>
         <low value="200704141515-0800"/>    <!-- Concern was documented on Apr 14, 2007 -->
      </effectiveTime>
      <entryRelationship typeCode="SUBJ">
        <observation classCode="OBS" moodCode="EVN">  <!-- Problem Observation  template-->
          ...lines omitted...
          <code code="64572001" displayName="Condition" codeSystemName="SNOMED-CT" codeSystem="2.16.840.1.113883.6.96"/>
          <statusCode code="completed"/>  <!-- This statusCode reflects the status of the observation itself -->
          <effectiveTime>
            <low value="20070414"/>    <!-- The low value reflects the date of onset -->
            <high value="20070415"/>    <!-- Presence of <high> element means the condition is resolved -->
          </effectiveTime>
          <value xsi:type="CD" code="29857009" codeSystem="2.16.840.1.113883.6.96" displayName="Chest pain"/>
        </observation>
      </entryRelationship>
  </act>
<section>
```

Is the chest pain currently active or resolved?

- statusCode values of problem in *Problem Section* template

```
<section>  <!-- Problem template -->
   ...lines omitted...
  <act classCode="ACT" moodCode="EVN">   <!-- Problem Concern Act  template -->
       ...lines omitted...
      <statusCode code="active"/>  <!-- Means this is of ongoing concern to the provider -->
      <effectiveTime>
         <low value="200704141515-0800"/>   <!-- Concern was documented on Apr 14, 2007 -->
      </effectiveTime>
      <entryRelationship typeCode="SUBJ">
        <observation classCode="OBS" moodCode="EVN">  <!-- Problem Observation  template-->
          ...lines omitted...
         <code code="64572001" displayName="Condition" codeSystemName="SNOMED-CT" codeSystem="2.16.840.1.113883.6.96"/>
         <statusCode code="completed"/> <!-- This statusCode reflects the status of the observation itself -->
         <effectiveTime>
           <low value="20070414"/>   <!-- The low value reflects the date of onset -->
           <high nullFlavor="UNK"/>    <!-- Presence of <high> element means the condition is resolved -->
         </effectiveTime>
         <value xsi:type="CD" code="29857009" codeSystem="2.16.840.1.113883.6.96" displayName="Chest pain"/>
        </observation>
      </entryRelationship>
  </act>
<section>
```

Is the chest pain currently active or resolved?

- Example: *Medication Activity* template

```
<substanceAdministration classCode="SBADM" moodCode="EVN">    <!-- ** Medication Activity template ** -->
  ...lines omitted...
  <effectiveTime nullFlavor="NP"/>
  <doseQuantity nullFlavor="NP"/>
  <consumable>
   <manufacturedProduct classCode="MANU">    <!-- ** Medication Information template ** -->
     ...lines omitted...
     <manufacturedMaterial>
      <code code="1154379" displayName="Atenolol Tablet" codeSystem="2.16.840.1.113883.6.88" codeSystemName="RxNorm"/>
     </manufacturedMaterial>
   </manufacturedProduct>
  </consumable>
</substanceAdministration>
```

- Other required fields that may have "nullFlavor" substitutes

Template Name	Data Element	DataType	Description
Vital Sign Observation	value	PQ	Value and unit of measure for the vital sign
Immunization Activity	effectiveTime	TS	Date/time at which immunization was given
Problem Observation	effectiveTime	TS	Date/time of problem onset and resolution
Medication Activity	doseQuantity	PQ	Dose of medication prescribed/administered
Medication Activity	effectiveTime	TS	Date/time when medication started and stopped

- Underspecification (redundancy) of negation methods in *Problem Observation* template

```
Representation 1:
<observation classCode="OBS" moodCode="EVN" negationInd="true">  <!-- ** Problem Observation template ** -->
 ...lines omitted...
 <effectiveTime>
  <low value="20130703"/>
  <high value="20130703"/>
 </effectiveTime>
 <value xsi:type="CD" code="88610006" codeSystem="2.16.840.1.113883.6.96" displayName="Heart murmur (finding)"/>
</observation>


Representation 2:
<observation classCode="OBS" moodCode="EVN">  <!-- ** Problem Observation template ** -->
 ...lines omitted...
 <effectiveTime>
  <low value="20130703"/>
  <high value="20130703"/>
 </effectiveTime>
 <value xsi:type="CD" code="301131000" codeSystem="2.16.840.1.113883.6.96" displayName="Heart murmur absent (situation)"/>
</observation>
```

- Underspecification (redundancy) of negation methods in *Problem Observation* template

```
Representation 1:
<observation classCode="OBS" moodCode="EVN" negationInd="true">  <!-- ** Problem Observation template ** -->
 ...lines omitted...
 <effectiveTime>
  <low value="20130703"/>
  <high value="20130703"/>
 </effectiveTime>
 <value xsi:type="CD" code="88610006" codeSystem="2.16.840.1.113883.6.96" displayName="Heart murmur (finding)"/>
</observation>


Representation 2:
<observation classCode="OBS" moodCode="EVN">   <!-- ** Problem Observation template ** -->
 ...lines omitted...
 <effectiveTime>
  <low value="20130703"/>
  <high value="20130703"/>
 </effectiveTime>
 <value xsi:type="CD" code="301131000" codeSystem="2.16.840.1.113883.6.96" displayName="Heart murmur absent (situation)"/>
</observation>
```

Consolidated CDA – Negation Issues

- Unclear scope of negation in *Immunization Activity* template

```
<substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="true">     <!-- ** Immunization Activity template** -->
  ...lines omitted...
  <effectiveTime value="20141215"/>
  <routeCode code="C28161" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Intramuscular injection"/>
  <doseQuantity value="50" unit="ug"/>
  <consumable>
    <manufacturedProduct classCode="MANU">    <!-- ** Immunization Medication template ** -->
      ...lines omitted...
      <manufacturedMaterial>
        <code code="33" codeSystem="2.16.840.1.113883.6.59" displayName="Pneumococcal polysaccharide vaccine" codeSystemName="CVX"/>
        <lotNumberText>14873</lotNumberText>
      </manufacturedMaterial>
      <manufacturerOrganization>
        <name>Health LS - Immuno Inc.</name>
      </manufacturerOrganization>
    </manufacturedProduct>
  </consumable>
  <performer>
    <assignedEntity>
      ...lines omitted...
      <assignedPerson><name><given>Harold</given><family>Jones</family></name></assignedPerson>
    </assignedEntity>
  </performer>
</substanceAdministration>
```

Consolidated CDA –
Negation Issues

- Unclear scope of negation in *Immunization Activity* template
- From HL7 v3 RIM specification for "negationInd" attribute:

The negationInd negates the Act as described by the descriptive properties (including Act.code, Act.effectiveTime, Observation.value, Act.doseQty, etc.) and any of its components...For example, a highly confidential order written by Dr. Jones, to explicitly not give "succinyl choline" for the "reason" (ActRelationship) of a history of malignant hyperthermia (Observation) negates the descriptive properties "give succinyl choline" (Act.code), but it is still positively an order and written by Dr. Jones and for patient John Smith, and the reason for this order is the patient's history of malignant hyperthermia. However, additional detail in descriptive attributes will limit the effective scope of the negation. For example, had the order not to give a substance included a doseQuantity, it would mean that the substance should not be given at that particular dose, but does not prohibit medication at any other dose.

- Absence of Explicit Negation for Certain C-CDA Templates
  - E.g., *Result Observation* template => for an imaging study result, there is no way to explicitly negate the observation of a pleural effusion
  - Senders must resort to other *ad hoc* methods
    1. Code: Imaging report observation
       Value: A specific code exists for the concept "no pleural effusion"
    2. Code: Pleural effusion
       Value (Boolean): false

- **Overlapping Coding Systems/Value Sets**
  - E.g., Coded value of the reported lab panel in *Result Organizer* template:
    - "SHOULD be selected from LOINC OR SNOMED CT, and MAY be selected from CPT-4; Laboratory results SHOULD be from LOINC or other constrained terminology named by the US Department of Health and Human Services Office of National Coordinator or other federal agency."
  - E.g., Coded value of the allergenic substance in *Allergy Intolerance* template:
    - "SHALL be from one of the following coding systems: NDFRT drug class codes, RxNorm ingredient codes, UNII ingredient codes, and SNOMED CT substance codes. The expectation for use is that the chosen concept identifier for a substance should be appropriately specific and drawn from the available code systems in the following priority order: NDFRT, then RXNORM, then UNII, then SNOMED CT."
  - E.g. Coded value of the familial disorder in Family History Observation template
    - SNOMED Finding: "Blood coagulation disorder (disorder)" [SCTID 64779008] OR
    - SNOMED Situation-with-Context: "Family history of blood coagulation disorder (situation)" [SCTID 108801000119109]

Consolidated CDA – Terminology Issues

- Optional Coding Systems/Value Sets
  - Certain important data elements have a "SHOULD" coding constraint rather than a "SHALL" coding constraint
    - <u>SHALL</u>: An absolute requirement
    - <u>SHOULD</u>: Best practice or recommendation. There may be valid reasons to ignore a [coding system requirement], but the full implications must be understood and carefully weighed before choosing a different course.

    - "SHOULD" coding constraints on:

Template	Data Element	Description
Vital Sign Observation	code	The type of reported vital sign (BP, HR, etc.)
Result Observation	code	The reported test (Serum sodium, X-Ray, etc.)
Result Observation	value/@code	The reported value of a non-numeric test result (e.g., Pneumococcus culture result)
Problem Observation	value/@code	The reported problem (Diabetes, CHF, etc.)
Procedure Activity	code	The procedure performed (Stent placement, Polypectomy, etc.)
Plan of Treatment	code	The planned action (Colonoscopy, Post-op visit, etc.)
Social History Observation	code	The type of reported attribute (Alcohol intake, Tobacco use, etc.)
Family History Organizer	relatedSubject/code	The family member whose history is reported (Aunt, Grandparent, etc.)

Consolidated CDA – Terminology Issues

- Underspecification of Post-Coordinated Expressions in Problem Observations

```xml
<observation classCode="OBS" moodCode="EVN">    <!-- ** Problem Observation template ** -->
  ...lines omitted...
  <effectiveTime>
    <low value="20130703"/>
    <high value="20130814"/>
  </effectiveTime>
  <value xsi:type="CD" code="233604007" codeSystem="2.16.840.1.113883.6.96" displayName="Pneumonia">
    <qualifier>
      <code code="363698007" codeSystem="2.16.840.1.113883.6.96" displayName="Finding site"/>
      <code code="41224006" codeSystem="2.16.840.1.113883.6.96" displayName="Left lower lobe of lung"/>
    </qualifier>
  </value>
</observation>
```

The observation/value and all the qualifiers together (often referred to as a post-coordinated expression) make up one concept. Qualifiers constrain the meaning of the primary code, and cannot negate it or change its meaning. Qualifiers can only be used according to well-defined rules of post-coordination and only if the underlying code system defines the use of such qualifiers or if there is a third code system that specifies how other code systems may be combined.

Thank you

Questions?

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