Potential Changes
mCODE STU 1 ➔ STU 2

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Purpose

- Provide an overview of changes either planned or under consideration for the next iteration of mCODE
- Backwards compatibility is an important goal, but fit for purpose even more so
- The changes discussed are tentative
Tentative Timeline

Begin August 2018

STU 1 Ballot Sept 2019

STU 1 Release March 2020

STU 2 Ballot May 2021

STU 2 Release Sept 2021

Jan 2019

Jan 2019

Jan 2020

Jan 2020

Jan 2021

Jan 2021

Begin August 2018

STU 1 Ballot Sept 2019

STU 1 Release March 2020

STU 2 Ballot May 2021

STU 2 Release Sept 2021

Genomics Reporting 1.0.0 release Nov 2019

transition to FHIR Shorthand

Submit data elements to USCDI Oct 2020

US Core 3.0.1 Sept 2019

Eliminated MedicationStatement

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Eliminated MedicationStatement
Starting Point: mCODE Standard for Trial Use (STU 1)

- Balloted Sept 2019; released March 18, 2020
mCODE STU 2 Objectives

- **Sustainment** -- keep up with FHIR (US Core, Genomics, Vocab...)
- **Improvement** -- incorporate feedback on STU 1 (HL7 JIRA issues)
- **Implementation** -- add examples, operations, conformance, tests
- **Good Growth** -- add selected data elements
- **Impact** -- submit mCODE elements to USCDI

OUTCOMES:

- Increased maturity, scope, and adoption
- STU 2 ballot in May 2021, with target release Sept 2021
Summary of **Expected Updates**

1. **Medication Resources** - Adopt US Core 3.1.0 approach
2. **Comorbidity Model** - STU1 approach was flawed; considering an approach that captures comorbid condition as a list
3. **CancerRelatedRadiationProcedure** - revisit how radiation type, delivery method, and technique are captured (ASTRO, AAPM)
4. **Genomics** - add DNA Change Type, inherit from Genomics IG (if timing permits)
5. **Other** - correct errors and oversights, certain relaxed cardinality, must support, naming, value sets, profile constraints, editorial corrections
Update: Medication Resources

- US Core made a significant change in September 2019 -- replacing MedicationStatement with MedicationRequest
  - Timing unfortunately coincided with mCODE STU 1 ballot
- Since mCODE aligns with US Core, we have to follow suit in STU 2
- This is not a backward compatible change
Update: Comorbidity Model

- STU 1 approach was flawed (see JIRA issues FHIR-27899 and FHIR-28298)
  - Consulted with several HL7 groups
- ComorbidCondition profile replaced by CancerRelatedComorbidities profile where comorbidities are represented as a list (in Observation.component)
  - Each element is either present, absent or unknown, plus a pointer to the actual condition (or code) if present
  - Split the enormous STU 1 ComorbidConditionVS into ~30 separate values sets corresponding to each comorbid condition category
- New PresentAbsentUnknown value set (answers for comorbidity categories)
- New ComorbidConditionCode and ComorbidConditionReference extensions
Update: CancerRelatedRadiationProcedure

- Revisiting how radiation type, delivery method, and technique are captured
- Current discussion with ASTRO and American Association of Physicists in Medicine (AAPM)
- Mapping to FHIR could present some challenges due to varying degrees of pre- and post-coordination and Procedure only having 'code' and 'method' fields
Update: Genomics

- Add DNA Change Type component to CancerGeneticVariant profile (and DNA Change Type Value Set)
- Correct code system canonical URL for HGNC according to HL7 terminology standards
- Currently under investigation: Derive from the HL7 Clinical Genomics Reporting IG profiles to reduce copying, assure alignment
  - Depends on the timing of their STU 2 release
Update: Less-Restrictive Cardinalities

Intended to lessen the chance of rejecting valid data:

- ComorbidCondition.verificationStatus 1..1 → 0..1
- CancerConditionParent.severity 0..0 → 0..1
- CancerConditionParent.bodySite 0..0 → 0..*
- CancerConditionParent.specimen 0..0 → 0..1
- CancerDiseaseStatus.bodySite 0..0 → 0..1
- TumorMarker.bodySite 0..0 → 0..1
- TumorMarker.hasMember 0..0 → 0..*
- TumorMarker.component 0..0 → 0..*
- TumorMarker.referenceRange 0..1 → 0..*
- TumorMarker.interpretation 0..1 → 0..*
- PerformanceStatusParent.dataAbsentReason 0..0 → 0..1
- PerformanceStatusParent.value[x] 1..1 → 0..1
- PerformanceStatusParent.referenceRange 0..0 → 0..*
Update: Additional Must Support Elements

Missed elements that should have been MS in STU 1:

- CancerDiseaseStatus.focus
- CancerDiseaseStatus. evidenceType
- TumorMarkerTest.focus
- CancerStageParent.focus
- CancerRelatedRadiationProcedure.terminationReason
Update: Naming

- **CancerDisorderVS → AnyCancerDisorderVS**
  - Could be primary or secondary (hence, any)
  - Id unchanged
- **LateralityVS → LocationQualifierVS**
  - Better align with FHIR BodyStructure location
  - VS to be expanded to include qualifiers for laterality, relative location, directionality, number, and plane
Update: Value Sets

- **CancerRelatedSurgicalProcedureVS**: Changed to intensional definition
- **CancerStagingSystemVS**: Added code representing AJCC version 8
- **TumorMarkerVS**: Added 3 codes for Epidermal growth factor receptor tests
- Comorbid condition value sets (mentioned earlier)
- **LocationQualifierVS**: expand to include qualifiers for relative location, directionality, number, and plane
Updates: Other

- CancerDiseaseStatus.basedOn - removed type constraint
- TumorMarkerTest.basedOn - removed type constraint
- ECOG, Karnofsky, Clinical Staging profiles: set Observation.category = #survey
- Pathologic staging profiles: set Observation.category = #laboratory
Summary of Additions

1. mCODE Patient Bundle -- all mCODE data for a given patient
2. Conformance -- define "mCODE compliant" in a testable way
3. New classes -- Tumor, Tumor Size, Adverse Event
4. Comprehensive example -- Patient journey in mCODE form
Addition: mCODE Patient Bundle

- Addresses the "Give me your mCODE data" question
- New profile, `mCODEPatientBundle` -- contains all mCODE data for a patient

Under investigation:

- How to define the bundle without depending on slicing by profile
New: Search and Operation Definitions

- GetPatientBundleOperation:

GET [base]/$mcode-patient-bundle/[id] to retrieve an mCODE Patient Bundle for a specified Patient
Addition: Conformance

1. "mCODE Patient" -- defines what patients are included in mCODE
2. Profile usage -- defines what information must conform to which profiles
3. API -- operations that can or must be supported by data sender and receiver
4. CapabilityStatement -- expresses implementation in a way testing software can use
5. Test suite -- actual tests that can be run to determine if an implementation is "mCODE conformant"
New: Conformance Criteria

- Defined mCODE scope in terms of "mCODE Patient"
- Added conformance statements for each profile, for example (PrimaryCancerCondition):

  "Condition resources associated with an mCODE patient with a Condition.code in the value set PrimaryOrUncertainBehaviorCancerDisorderVS MUST conform to this profile. Beyond this requirement, a producer of resources SHOULD ensure that any resource instance associated with an mCODE patient that would reasonably be expected to conform to this profile SHOULD be published in this form, for example, when employing a code that extends the PrimaryOrUncertainBehaviorCancerDisorderVS value set. Any resource intended to conform to this profile SHOULD populate meta.profile accordingly."

- Actors implementing mCODE SHALL support CancerPatient, PrimaryCancerCondition, and MCODEPatientBundle UNLESS the necessary data to populate them is typically not available in their system.
New: CapabilityStatements

- Custom operations defined:
  1. List all mCODE Patients in the system*
  2. Retrieve an mCODE Patient Bundle ($mcode-patient-bundle)
- Several methods defined for #1, each with a capability statement
  - To be determined: whether mCODE can depend on meta.profile
Addition: Comprehensive Persona-Based Example

Intended to help implementers translate real-world situations into mCODE

Patient M is a 55 year old non-Hispanic white female with a past medical history significant for depression, a 20-pack-year history of smoking (current smoker), anxiety, and hypertension. Her family history was significant for a maternal aunt with ovarian cancer at age 69, a sister with breast cancer at age 64, and deceased paternal uncle due to pancreatic cancer.

She presented for routine screening mammography in March 2018. Performance status was ECOG 0. An abnormality was detected, followed by ultrasound-guided biopsy which revealed a Grade 2 invasive ductal adenocarcinoma, ER positive, PR negative, HER2 negative. Pre-operative workup revealed no other disease in either breast. Genetic counseling ordered a 7 gene panel, which revealed a pathogenic variant in PALB2 (c.3549C>A).1

A partial mastectomy was performed, revealing a 2.5 cm tumor with no lymph-vascular invasion and negative margins of excision. Ductal carcinoma in situ was noted, also completely excised. Three sentinel lymph nodes were excised and were negative for metastatic carcinoma. The primary tumor was staged as cT3N0.

A 21-gene RT-PCR assay yielded a recurrence score of 47. She received four cycles of doxorubicin (60 mg/m² IV) and cyclophosphamide (600 mg/m² IV) followed by paclitaxel (175 mg/m² IV) (AC-T), administered on a dose-dense schedule. She subsequently received whole breast radiation therapy with regional nodal irradiation. Following RT, she began anastrozole (1 mg daily).

The patient is two years out from surgery and has undergone surveillance imaging and has no evidence of recurrent disease or new imaging. She continues to take adjuvant endocrine therapy (anastrozole).

26 Interrelated Resources
Addition: Tumor Size

- Even though size is a factor in T stage, the actual measured size is sometimes needed in care pathways and clinical trials
- Not certain if this meets the "minimal" criteria in mCODE
- Experimental profiles:
  - Tumor (derived from BodyStructure)
  - TumorSize (derived from Observation)
Addition: Adverse Event

- Support adverse event / adverse drug reaction data capture
  - initial focus on representation of CTCAE based on FHIR AdverseEvent resource
  - Challenge: FHIR R4 and R5 AdverseEvent resources are quite different
- Use Cases:
  - iCAREdata clinical trials
  - FDA Reporting
Final Note

- There may be additional issues as users experience STU 1
- There may be additional items from mCODE Executive Council or CodeX
- The door for STU 2 closes in February -- any significant changes should be in motion before the end of the year

- Work in progress can be viewed here: [http://build.fhir.org/ig/HL7/fhir-mCODE-ig/branches/master/index.html](http://build.fhir.org/ig/HL7/fhir-mCODE-ig/branches/master/index.html)
  - Note: Data dictionary has not been updated in the above draft version