mCODE alignment

mCODE is a Domain of Knowledge IG:

> The purpose of this IG is to show how to represent clinical concepts generally, not to have a complete set of agreements for interoperable exchanges.

ICHOM is a Domain of Knowledge IG as well, which implies that the alignment will be done at a high level only.

Vadim Peretokin's notes:

0.1. Background

HL7 sponsorship and input from Clinical Interoperability Council (first council) and Clinical Information Modeling Initiative is gratefully acknowledged, with special thanks to Richard Esmond, Laura Heermann Langford, and Lindsey Hoggle. Most of the work was done in 2019, things seem to be quieter since then.

IG created for a US context of cancers with the support American Society of Clinical Oncology (ASCO), twenty leading clinical experts in oncology, radiology, surgery, and public health developed two use cases, they aligned with several pre-existing standards, nomenclatures, and guidelines were consulted in the development of this specification, including: but an important note on the modelling is that - Down-scoping was done based on whether the data would be stored or capture in an electronic health record (EHR, and if it would place undue documentation burden on clinicians.

This implementation guide is a Domain of Knowledge IG. The purpose of this IG is to show how to represent clinical concepts generally, not to have a complete set of agreements for interoperable exchanges.

Domain of Knowledge IGs are seldomly used and the mCODE one seems to be the first one that does it. There's just two other IGs like this, another one that builds on mCODE.

IG cannot be there used for purposes of interop, not without further refinement. This refinement work is what the CodeX project at HL7 is going.

Timing information for example isn't included, since mcode is just about the clinical concepts.

However it is pretty detailed. MASSIVE amount of modeling work done, we should seek to leverage it.

why not done? I don't have the concrete answer from the authors, but my hunch is that it's not complete. Modelling cancer is a huge amount of work.

Another guess is that they don't want to impose a working model, but instead wanted to provide the basis for one.

US scope, builds upon US core profiles. Not just for demographics, but even lab results and etc build on US core profiles, which makes it an issue for re-using internationally. However we should seek to align so a FHIR resource instance that's conformant to mCODE should be also conformant to ICHOM to ensure interoperability and lower costs for implementers.

0.2. Content
Content scope: mCODE is for all cancers, whereas ICHOM standard sets cover several types of cancers and other diseases as well such as depression, dementia and more. In this regard, ICHOM covers a lot more.

mCODE is focused towards research data, whereas ICHOM is for patient outcomes as well as research data - so ICHOM has a bigger coverage for the scope of data.

mCODE is a step towards capturing research-quality data from the treatment of all cancer patients. This would enable the treatment of every cancer patient to contribute to comparative effectiveness analysis (CEA of cancer treatments by allowing for easier methods of data exchange between health systems. While mCODE ultimately is meant to be applicable across all types of cancer, the initial focus (and both use cases) has been on solid tumors. At this time, mCODE does not include patient reported outcomes.

The IG models concepts in 6 areas:

- **Demographics**
- **Diseases**
- **Health Assessment Group**
- **Genomics Group**
- **Cancer Treatments Group**
- **Outcomes Group**

### 0.3. Demographics

Demographics - including date of birth, gender, zip code, race, and ethnicity

Relevant to ICHOM:
0.4. **Diseases**

The mCODE Disease Characterization group includes data elements specific to the diagnosis and staging of cancer. This includes:

- **Cancer Diagnosis** - the date and location (body site/position and laterality) of the cancer diagnosis.
- **Tumor Characteristics** - histological classification, morphology, and behavior of the tumor cell, compared to that of a normal cell.
- **Cancer Stage** - describes the severity of an individual’s cancer based on the magnitude of the original (primary) tumor as well as on the extent cancer has spread in the body. Understanding the stage of the cancer helps doctors to develop a prognosis and design a treatment plan for individual patients. Staging calculations leverage results from the previous two categories, along with prognostic factors relevant to the cancer type, in order to assess an overall cancer stage group (source: AJCC).

Depending on the EHR and provider organization, different code systems may be used, such as:

- Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT)
- International Classification of Diseases, 10th version, Clinical Modifications (ICD10CM)
- International Classification of Diseases for Oncology, 3rd version (ICDO3)
- Because the use of these code systems vary in different institutions, mCODE supports all three.

**Relevant to ICHOM:**

Data set looks similar at a glance. Both record information about the tumor, staging, HER2 receptor and so on.

0.5. **Health assessments**

The mCODE Assessment group contains information related to the patient’s general health, before and during treatment.

**Comorbidities**

Comorbidities are important in the prognosis and treatment. Comorbid conditions in mCODE are aligned with the Elixhauser Comorbidity Index (based on ICD10-CM).

**Laboratory Tests**

Many laboratory tests could be relevant to an individual with cancer. mCODE includes results from two common laboratory panels, the Complete Blood Count (CBC Automatic or Manual Differential) and Comprehensive Metabolic Panel (CMP. Follows US Core guidelines for lab tests.

**Vital Signs**

Vital signs are measurements of the most essential, or “vital” body functions. For mCODE, blood pressure, body height, and body weight are believed to be most critical to assessment and treatment.

**Performance Assessments**

mCODE supports the Eastern Cooperative Oncology Group (ECOG Performance Status) and Karnofsky Performance Status (KPS. Because performance assessments may be performed more than once over a period of time, multiple instances may exist for a single patient.
Relevant to ICHOM:
Also records comorbidities, vital signs. Doesn't cover lab tests, and I'm uncertain about performance assessments.

Genomics
mCODE includes genomics-related data elements needed inform cancer assessment and treatment options. The profiles are based on the HL7 CGWG Clinical Genomics Reporting Implementation Guide. Four profiles relate to the capture of clinical genomics data:

**CancerGenomicsReport** - contain results of genomic analyses. Genomic reports vary in complexity and content, as simple as the results for a single discrete variant to complex sequences.

**CancerGeneticVariant** - used to record variants that could be found from tests that broadly analyze genetic regions (e.g.: exome tests) and stores results for any variants that could have been found. The region in which the variant was found could be specified in the RegionStudied attribute of the GenomicsReport profile.

**GenomicRegionStudied** - used to record the portion(s) of the genome that was tested for variants.

**GeneticSpecimen** - describes a specimen collected for a genomics test. mCODE genomics elements should be seen as data that could be available for exchange. It is not assuming all of the data elements need to be captured and exchanged.

Relevant to ICHOM:
HER2 status and genetic mutation maybe, but otherwise not so much coverage.

Treatment
The Treatment group includes reporting of procedures and medications used to treat a cancer patient, or relevant to that treatment. Treatments fall into three classes: medications, surgery, and radiotherapy.

Medications
Represented in RxNorm (FDA-approved only) and NCI Thesaurus (NCIT for clinical trials drugs
US Core gives preference to representing medications using the National Library of Medicine (NLM RxNorm terminology - a coding standard established by the Office of the National Coordinator (ONC for the exchange of drugs. However, RxNorm is restricted to FDA-approved drugs and does not include clinical trial drugs. mCODE allows for the inclusion of other code systems like the NCI Thesaurus (NCIT to represent clinical trial oncology drugs. Two profiled resources are used to record medications: MedicationRequest and MedicationAdministration. In version 3.1 and later, US Core does not use MedicationStatement, preferring to represent patient-reported medications using MedicationRequest. mCODE uses MedicationAdministration for drugs administered by clinicians, as often the case for chemotherapy drugs.

Surgery
Not all surgical procedures are relevant to treatment of cancer patients. To limit the scope of reported surgeries, mCODE uses the concept of cancer-relatedness. Only surgeries whose reason traces back to a cancer condition are in scope. mCODE does not at this time have detailed profiles for the many types of cancer-related surgeries.

Radiotherapy
A radiation oncology work group convened under CodeX FHIR Accelerator has helped create new profiles and value sets for radiotherapy. The group included American Society for Radiation Oncology (ASTRO?, American Association of Physicists in Medicine (AAPM, Integrating Healthcare Enterprise - Radiation Oncology (IHE?RO?, Varian, Elekta, Epic, and Wemedoo. The group helped defined value sets for modality and technique for external beam (teleradiotherapy) and internal radiotherapy (brachytherapy), as well as profiles for delivery of both types of treatment. To limit the scope, mCODE focused on high-level summarization of the treatment given, and avoids many details of the treatments. Ordering workflows are out of scope.

Relevant to ICHOM:
Yes, treatment is covered - radiotherapy and surgery, but medications is not relevant for the breast cancer set.
0.6. Outcomes

Recording patient outcomes in mCODE involves disease status, tumor size, and date of death. Other common outcome measures, such as progression-free survival, time to recurrence, and overall survival, can be derived from time-indexed observations of disease status. The date of diagnosis is also required for some derived measures (see Disease Characterization). At this time, mCODE does not include patient reported outcomes.

Relevant to ICHOM:

Outcomes are most definitely covered, and in far more detail that mCODE by the virtue of including patient-reported outcomes. In fact at a guess about half of ICHOM's breast cancer data points are focused on patient-reported outcomes.

0.7. Profiles:

Here below the profiles are assessed to determine whether they could be useful for the ICHOM modelling. The profiles are ordered by their relevance, starting with the ones that are most useful for ICHOM.

**TNM Distant Metastases Category Profile:**

Category describing the extent of a tumor metastasis in remote anatomical locations, based on evidence such as physical examination, imaging, and/or biopsy.

**Elements:**
- Status
- Code
- Subject
- Focus
- Effective
- Value
- Method

**Resources:** Observation

**Relevant to ICHOM:** Yes

**TNM Primary Tumor Category Profile:**

Category of the primary tumor, based on its size and extent, based on evidence such as physical examination, imaging, and/or biopsy.

**Elements:**
- Status
- Code
- Subject
- Focus
- Effective
- Value
- Method

**Resources:** Observation

**Relevant to ICHOM:** Yes

**TNM Regional Nodes Category Profile:**

Category of the presence or absence of metastases in regional lymph nodes, based on evidence such as physical examination, imaging, and/or biopsy.

**Elements:**
- Status
- Code
- Subject
- Focus
- Effective
Cancer Stage Group Profile:

The extent of the cancer in the body, according to a given cancer staging classification system, based on evidence such as physical examination, imaging, and/or biopsy or based on pathologic analysis of a specimen.

Elements:
- Status
- Code
- Subject
- Focus
- Effective
- Value
- Method

Resources: Observation
Relevant to ICHOM: Yes, combined with TNM staging

Cancer Patient Profile:

A patient who has been diagnosed with or is receiving medical treatment for a malignant growth or tumor. This is the most essential profile in mCODE, since it is referenced by many other profiles. The only difference between the mCODE Patient profile and the [US Core Patient Profile] is that Patient.deceased is a [must-support] element in mCODE.

Elements:
- Identifier
  - System
  - Value
- Name
  - Family
  - Given
- Telecom
  - System
  - Value
  - Use
- Gender
- Birth Date
- Deceased
- Address
  - Line
  - City
  - State
  - Postal Code
  - Period
- Communication language

Resources: Patient
Relevant to ICHOM: Yes, but we could also use US core

Cancer-Related Surgical Procedure Profile:

A surgical action addressing a cancer condition. The scope of this profile has been narrowed to cancer-related procedures by constraining the reasonReference and reasonCode to cancer conditions, one of which is required.

Elements:
- Treatment intent
- Status
- Code
- Subject
- Performed
- Reason Code
- Reason Reference
- Body Site
Genomics Report Profile:

Genomic analysis summary report. The report may include one or more tests, with two distinct test types. The first type is a targeted mutation test, where a specific mutation on a specific gene is tested for. The result is either positive or negative for that mutation. The second type is a more general test for variants. This type of test returns the identity of variants found in a certain region of the genome.

Elements:
- Status
- Subject
- Effective
- Issued
- Performer
- Specimen
- Result
  - Genomic Variant
  - Genomic Region Studied

Resources: Diagnostic Report
Relevant to ICHOM: Yes, comparable to genetic mutation

Cancer-Related Medication Administration Profile:

An episode of medication administration for a patient whose condition is related to a primary or secondary cancer condition. In the context of chemotherapy drugs, the medication administration in most cases is performed and documented by the provider.

Elements:
- Treatment intent
- Termination Reason
- Status
- Medication
- Subject
- Effective
- Reason Code
- Reason Reference

Resources: MedicationAdministration
Relevant to ICHOM: Could be interesting in regards to chemotherapy

Primary Cancer Condition Profile:

Records the the primary cancer condition, the original or first tumor in the body (Definition from: [NCI Dictionary of Cancer Terms]. Cancers that are not clearly secondary (i.e., of uncertain origin or behavior) should be documented as primary.

Elements:
- Asserted Date
- Histology Morphology Behavior
- Clinical Status
- Verification Status
- Category
- Code
- Body Site
  - Location Qualifier
  - Laterality Qualifier
- Subject
- Stage
  - Assessment

Resources: Condition
Relevant to ICHOM: Yes, not as extensive though
Radiotherapy Course Summary Profile:
A summary of a course of radiotherapy delivered to a patient. It records the treatment intent, termination reason, modalities, techniques, number of sessions, and doses delivered to one or more body volumes. Whether the course has been fully delivered or stopped is indicated in the status element.

Elements:
- Treatment Intent
- Termination Reason
- Modality and Technique
  - Modality
  - Technique
- Actual Number of Sessions
- Dose Delivered to Volume
  - Volume
  - Total Dose Delivered
  - Fractions Delivered
- Status
- Subject
- Performed
- Reason Code
- Reason Reference
- Body Site

Resources: Procedure

Relevant to ICHOM: Yes, not as extensive though

Tumor Size Profile:
Records the dimensions of a tumor

Elements:
- Subject
- Focus
- Effective
- Method
- Specimen
- Component
  - Tumor Longest Dimension
  - Tumor Other Dimension

Resources: Observation

Relevant to ICHOM: Yes, not as extensive though

Tumor Marker Test Profile:
The result of a tumor marker test. Tumor marker tests are generally used to guide cancer treatment decisions and monitor treatment, as well as to predict the chance of recovery and cancer recurrence.

Elements:
- Status
- Code
- Subject
- Effective
- Value
- Data Absent Reason
- Specimen

Resources: Observation

Relevant to ICHOM: yes, this profile is too generic, we have to further specify it according to the ICHOM set

Secondary Cancer Condition Profile:
Records the history of secondary neoplasms, including location(s) and the date of onset of metastases. A secondary cancer results from the spread (metastasization) of cancer from its original site (Definition from: NCI Dictionary of Cancer Terms).

Elements:
• Extension
  • Asserted date
  • Histology morphology behavior
  • Related primary cancer condition (reference)
• Clinical status
• Verification status
• Category
• Code
• Body site
  • Location qualifier
  • Laterality Qualifier
• subject

Resources:

Relevant to ICHOM: It may be relevant in regards to recurrence, but does not really cover the same things

**Comorbidities Elixhauser Profile:**

Comorbid condition checklist and optional risk score, using Elixhauser comorbidity categories as defined by the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (H-CUP).

Elements:

Resources: Observation

Relevant to ICHOM: Some overlap, but different lay-out from co-morbidities in ICHOM Dataset.

**ECOG Performance Status Profile:**

The Eastern Cooperative Oncology Group (ECOG) Performance Status represents the patient's functional status and is used to determine their ability to tolerate therapies in serious illness, specifically for chemotherapy.

Elements:

Resources: Observation

Relevant to ICHOM: Not specific enough for ICHOM, for ICHOM this is captured in PROMs (Questionnaires)

**Genomic Region Studied Profile:**

A subset of genes or genomic regions of interest in a targeted resequencing study.

Elements:

• Status
• Subject
• Effective
• Value
• Data Absent Reason
• Component
  • Code
  • Value
  • Gene Mutation
  • Gene Studied
  • DNA region description
  • DNA ranges Examined
  • Genomic region coordinate system
  • Genomic Reference Sequence

Resources: Observation

Relevant to ICHOM: out of scope

**Genomic Specimen Profile:**

Genomic Region Studied Profile: A small sample of blood, hair, skin, amniotic fluid (the fluid that surrounds a fetus during pregnancy), or other tissue which is excised from a subject for the purposes of genomics testing or analysis.

Elements:

• Related Condition
Genomic Variant Profile:
An alteration in the most common DNA nucleotide sequence. The term variant can be used to describe an alteration that may be benign, pathogenic, or of unknown significance. The term variant is increasingly being used in place of the term mutation. Variants can be computed relative to reference sequence assembly from which it was identified.

Elements:
- Evidence Type
- Status
- Subject
- Focus
- Effective
- Value

Resources: Observation
Relevant to ICHOM: out of scope

Cancer Disease Status Profile:
A clinician's qualitative judgment on the current trend of the cancer, e.g., whether it is stable, worsening (progressing), or improving (responding). The judgment may be based a single type or multiple kinds of evidence, such as imaging data, assessment of symptoms, tumor markers, laboratory data, etc.

Elements:
- Evidence Type
- Status
- Subject
- Focus
- Effective
- Value

Resources: Observation
Relevant to ICHOM: Out of scope

Karnofsky Performance Status Profile:
The Karnofsky Performance Status (KPS) is a tool used to measure a patient's functional status. It can be used to compare the effectiveness of different therapies and to help assess the prognosis of certain patients, such as those with certain cancers. The KPS score ranges from 0 to 100 in intervals of 10. Higher scores are associated with better functional status, with 100 representing no symptoms or evidence of disease, and 0 representing death.

Elements:
- Status
- Subject
- Effective
- Value
- Interpretation

Resources: Observation
Relevant to ICHOM: Out of scope

Cancer-Related Medication Request Profile:
A record of a medication prescription or consumption associated with cancer treatment. The medication may reported by the prescriber, prescribing organization, or patient. It does not have to be directly observed.

Elements:

Resources:
Relevant to ICHOM: Out of scope
Radiotherapy Volume Profile:
A volume of the body used in radiotherapy planning or treatment delivery.

Elements:
- Identifier
- Display Name
- Morphology
- Location
- Location Qualifier
- Description

Resources: BodyStructure

Relevant to ICHOM: Out of scope

Tumor Profile:
Identifies a tumor that has not been removed from the body. Whenever possible, a single resource conforming to this profile will be used to track a tumor over time (as opposed to creating new Tumor-conforming BodyStructure resources each time that tumor is measured). Use TumorSpecimen to represent the tumor after removal from the body.

Elements:
- Extension
  - Related Condition
- Identifier
- Location
- Location Qualifier
- Patient

Resources: BodyStructure

Relevant to ICHOM: Out of scope

Tumor Specimen Profile:
Represents a tumor after it has been removed from the body. If there is a Tumor resource representing the tumor before it was removed from the body, use `identifier` to associate this TumorSpecimen with that Tumor resource.

Elements:
- Related Condition
- Identifier
  - Tumor Identifier
- Status
- Subject
- Collection
  - Body Site
    - Location Qualifier
    - Laterality Qualifier

Resources: Specimen

Relevant to ICHOM: Out of scope

0.8. ValueSets

Relevant ValueSets of mCODE that can be useful for ICHOM:

- Clinical or Pathological staging:
  - General: http://hl7.org/fhir/us/mcode/ValueSet/mcode-observation-codes-stage-group-vs
  - Tumor: http://hl7.org/fhir/us/mcode/ValueSet/mcode-observation-codes-primary-tumor-vs

- TNM staging (according to AJCC)

- Laterality:

- Presence of phenomena:
Outstanding questions

- Condition vs Observation modelling for representing staging - Condition seems like a better fit?
- How is clinical vs pathological measurement conveyed within each Observation?
- TNM staging modelling - differences valuesets and profile structures. How to align?
- We used the mCODE profiles: cancer-related medication administration, medication request and surgical procedure to model most of our treatment variables. Is that a good fit?
- mCODE created a treatment intent extension (e.g. palliative or curative care). For the ICHOM set we differentiate between neo-adjuvant or adjuvant therapy intent and modelled this in reasonCode. Would mCODE recommend that as well?
- Based on recent updates of the BRC set we now have elements for MolecularProfiling, would that fit in any of the mCODE profiles?