Requesting Clinical Content for Developing CIMI Models
Version 1.00

Handbook describing how to gather and format clinical content for model development
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Introduction

Background
Patient care doesn’t take place at a single site nor is it provided by a single medical specialty. Complex care involves numerous providers collaborating over time which requires the ability to exchange patient information that can be integrated into the health record to increase knowledge. Most existing medical record communications rely on Faxes, PDFs, Clinical Document Architecture (CDA) documents and HL7 v2.x messages which succeed at exchanging information, but places a high-burden on clinician’s attention to insure that critical truths don’t fall through the cracks. Exchanging a document which can’t be understood by the computer means that a person must read each line to understand actual information. Patient care data that is text only cannot facilitate clinical decision support, calculations, or be used to navigate through the clinical workflow. In situations where this may be feasible, patient information collected in one environment should carry with it the context and definition of how it was originally generated to ensure its data integrity. This is considered Interoperability.

Semantic interoperability implies that the meaning of the information, in the context it was generated, is properly preserved in the transfer. This provides the level of integration between systems that can support logical and formulaic processing and automation that is needed to bring the full value of modern science to bear on information that spans across software systems. No patient’s treatment takes place at a single site or is provided by a single medical specialty. Complex care involves numerous providers collaborating over time. For example, a physician would like to track and trend a patient’s hemoglobin A1C regardless of where the test was performed. When the test is performed by different labs, tracking cannot be done without interoperability standards.

Although the clinical narrative captured in current generation healthcare systems can support routine care, structured data is needed to support reliable and consistent logic and calculations needed for clinical decision support, quality metrics, clinical research and complex formula based payment models. The achievement of semantic interoperability requires the adoption and use of data standards and exchange all along the care continuum. The Fast Health Interoperability Resources (FHIR) looks to improve on what was accomplished through Clinical Document Architecture (CDA), which is, to provide for the exchange of a more consistent and computable structured medical record.

The Clinical Information Modeling Initiative (CIMI) is a Health Level Seven (HL7) group that is defining a library of common or standardized information that includes the terms with consensus definitions and the information that is associated with that term. For example, a blood pressure measurement should contain the systolic and diastolic measurements. The measurement may also include the body position, body location or cuff size. The modeling formalism is designed to include the context of collection and qualifying attributes. This is called a detailed clinical information model (DCM). CIMI was established to improve the interoperability of healthcare information systems through shared implementable clinical information models. The development (and governance) of these CIMI models is performed by clinical domain experts assisted by medical informaticists and standardization process administrators. FHIR provides the details of ‘how’ medical records are exchanged and CIMI provides the details of ‘what’ will be exchanged.
Purpose
The purpose of this document is to provide a guide to the process for preparing and submitting clinical content that can be standardized and used among and across clinical settings. This is an important first step in establishing a CIMI project for a clinical use case. The path to developing standardized clinical content will include the development of a Domain Analysis Model (DAM) - defining clinical content, Clinical Information Modeling Initiative (CIMI) models - putting the content into a structure using the CIMI formalism, and Fast Health Interoperability Resource (FHIR) Profiles- packaging content into machine readable information.

This document is designed as a step-by-step guide for project inception, clinical data harmonization, and formatting the clinical content request for CIMI models. The spreadsheet will be used to create detailed clinical models (DCMs) and constituent parts of a Domain Analysis Model (DAM).

Additional Resources
Clinicians provide the relevant clinical experience and expertise that fuels the clinical modeling process, but they are not expected to shoulder the technical and administrative work that is involved in authoring the final computer language that is needed to express those truths in the various syntaxes. It is however useful for clinical subject matter experts to have a basic comfort level with the various terms and concepts that come up in these conversations.

In recognition of this, we will be creating a number of documents that have been authored to offer simple answers to common questions and give a high-level overview of the modeling process. Below is a link to the clinical modeling primer:

Clinical Modeling Primer & FAQ

Objective
This document will provide clinical teams a step-by-step process for evaluating and entering their data, such as questionnaires or documentation templates, into model request templates. The model request templated data will be used to develop a DAM, perform mapping to the standard terminologies such as Logical Observations Identifiers Names and Codes (LOINC) and SNOMED Clinical Terms (CT) and to develop CIMI models.

Target Audience
The document is written for subject matter experts with limited informatics, terminology or information modelling expertise. The primary responsibility of the clinicians is to provide the expertise and experience to an organized process whose goal is to extract and document the fundamental truths related to the human body, disease processes and treatment options for a targeted clinical topic.

Clinicians need never worry about the more esoteric technical challenges of authoring the clinical model semantics; that will be the responsibility of the Informaticists and Terminologists on the team. Clinical Modeling projects will contain team members with a variety of different skills. Informaticists, Terminologists, Clinical Subject Matter Experts (SME’s) and a project leader each play their own unique role in the modeling process. The SMEs are responsible for initiating the teams.
Step-by-Step Process

The diagram below illustrates the steps required for a CIMI clinical content request. It is important to note that some organizations may have completed steps 1-5 prior to engaging with HL7 CIMI. Therefore, they should skip to number six.

1. Engage stakeholders

The CIMI models are intended to be prescriptive across a specific specialty. Therefore, it is pertinent to identify and approach subject matter experts (SMEs) within the clinical area to participate. Participants will be involved in defining the data elements, documenting the meaning of those elements, and providing evidence for definitions. Medical informaticists can then develop the clinical models, and validate and perform quality assurance (QA) for the models after development. This may include, but is not limited to, stakeholders in healthcare (various types of clinicians), research, public health, quality, government, academia, and health agencies.

This process may require stakeholders from multiple groups to come to a consensus on the data or term name, definitions, and allowable permissible values.

The steps needed to engage stakeholders are:

- Identify pertinent experts
- Organize outreach to the relevant communities
- Arrange kick-off meeting
- Define scope and use cases for the CIMI models
2. **Project Overview**

   Provide an overview of the project, program, research, registry, etc. Describe purpose (charter) the aims and objectives of the project. Include the situation, background and the work to be completed and indicate who the key stakeholders of the project will be. It is recommended to first determine a scope that is small enough to accomplish within 3-6 months. If the domain is large the effort can be divided into phases.

   Identify and document the ‘use cases’. Use cases should be based on clinical activity. This is an iterative process that will likely continue throughout model development. The best results come from starting with a relatively compact set of use cases that are well understood, and then continue to iteratively add to this list as needed throughout the process.

3. **Gathering data and credible evidence**

   The clinical data being modeled is gathered. Data includes conditions, diagnoses, and symptoms, observations (assessments) lab tests, procedures and answers/values. The data may be in a template, on a form, within a data base, a clinical guideline, or other format. Credible evidence assists in ensuring the accuracy, currency, and completeness of the data. Data sources include:

   - Documentation forms
   - Current literature
   - Research frameworks from recent studies
   - Final data sets from completed studies
   - Clinical data standards / regulatory requirements

4. **Aligning information sources to identify and resolve discrepancies and redundancies**

   Collate the data from all sources, identify and resolve the duplicates. Look for string matches and determine if two proposed data elements are the same thing. Duplicates may also be synonyms for example “tip of nose” is a synonym for “apex of nose”.

5. **Define the data**

   Each datum needs a text definition unless already defined industry-wide, such as gender. Understanding the meaning of each item will assist in identifying synonyms and future matching to standard terminologies such as SNOMED CT and LOINC. For example “frequent urination” may or may not be the same as “polydipsia”.

   As previously stated the project should be scoped so that it can be completed within 3-6 months (no more than 100 terms). The focus should be on the clinical specialty terms rather than common terms across domains such as demographic data (i.e. data of birth, gender, and race) because these are defined and can be used across domains.

6. **Populate the data request spreadsheet**

   The data request spreadsheet is in a standardized template format. The columns are used throughout the content and development process for downstream steps such as comparing your clinical content to
DCMs already created, terminology matching and mapping, and model development. You will receive the document with sample data. (Please delete the sample content before submitting to CIMI.) The main tab is the attributes tab. On this tab, enter the question and answer list (value set) name. See descriptions below or the sample spreadsheet.

Each row requires a clinical definition describing what is actually being modeled. The definitions are used during terminology matching to assist in determining a meaning match.

**Category**
Each row, no matter what the type should be given a category. This is a category, or classification, of clinical data that the application/service needs to capture. e.g., vitals, medical history, social history, labs, etc. Alternatively, the application/service may be operating at a higher level of abstraction, e.g., observation, procedure, etc. This column is intended to capture requirements -- the informaticists will assess the requirements and define models. It will also assist in sorting, assembling and nesting the data in the domain analysis and CIMI models. Note that the models may not necessarily be named, divided, and characterized the same as the information entered on this spreadsheet.

1. Enter the category of the term or data. For example a list of terms may be classified as assessment, medical history, orders, social history, labs, or vitals

**Diagnosis, symptom, conditions and procedures**
This type of data is used to describe a condition that is present or absent.

1. Enter the condition in the “**Term/Attribute Name**” column
2. Enter a definition in the “**Definition**” column.
3. Enter PresentAbsent in the value set name

There are no other columns to complete for this type of data.

**Questions with a value set answer**

1. Enter the question (observation) in the “**Term/Attribute Name**” column
2. Enter the “**Definition**” column.
3. Enter the value set name in the “**Value Set Name**” column. If the value set exists in the Value Set Authority Center (VSAC) use the name in VSAC.
4. If the value set exists put the value set identifier, such as a VSAC OID in the “**Value Set Identifier**” column.

New value sets require that each value be listed. These are entered in the “Value Set” tab. Enter the “**Value Set Name**”, the “**Value**” and the “**Definition**” for the value (unless it is commonly known such as the gender of female).

**Quantitative data**
Quantitative data is data that is resulted with a unit of measure.

1. Enter the question (observation) in the “**Term/Attribute Name**” column
2. Enter the “**Definition**” column.
3. Enter the unit of measure in the “**Unit of Measure**” column
**Ratio quantitative data**

Ratio data is a specialization of quantitative data the difference being there is both a numerator and a denominator.

1. Enter the question (observation) in the “Term/Attribute Name” column
2. Enter the “Definition”
3. Enter the numerator unit of measure in the “Numerator Unit of Measure” column (e.g. ml, %, mg/dL)
4. Enter the denominator unit of measure in the “Denominator unit of Measure” column

This concludes the content request process. Once the spreadsheet is complete, the project description, use cases and spreadsheet will be analyzed by terminology and model developers. This document only describes the first swimlane of the model development process. The next steps after request include analysis, terminology mapping, terminology creation, CIMI model mapping, and CIMI model creation (for new models). Once a model has been completed it will be placed in an on-line repository and all interested clinical experts will be invited to review it and suggest corrections and additions. When all issues have been resolved, the model is made available for the creation of implementation specific artifacts (Java classes, FHIR profiles, etc.) which are then used in creation of executable software.