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Implementing Data-Modeling Changes to FHIR Profiles and Consolidated CDA Templates To Improve Patient Safety

A Two-Year Roadmap

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September 29, 2018

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Contents

1 Introduction

This whitepaper is the third in a series of documents addressing certain data-modeling issues identified in FHIR resources and C/CDA templates that can compromise patient safety. The previous two whitepapers described the data-modeling issues in question[1] and proposed future enhancements to FHIR profiles and C/CDA templates to address these issues[2]. This whitepaper lays out a two-year roadmap for sequentially implementing the prescribed enhancements. By following this roadmap, the VA, or any healthcare system that intends to exchange patient data using FHIR profiles and C/CDA templates, can create derived FHIR profiles and C/CDA templates that are compatible with current national standards, but mitigate certain of patient-safety risks in these standards.

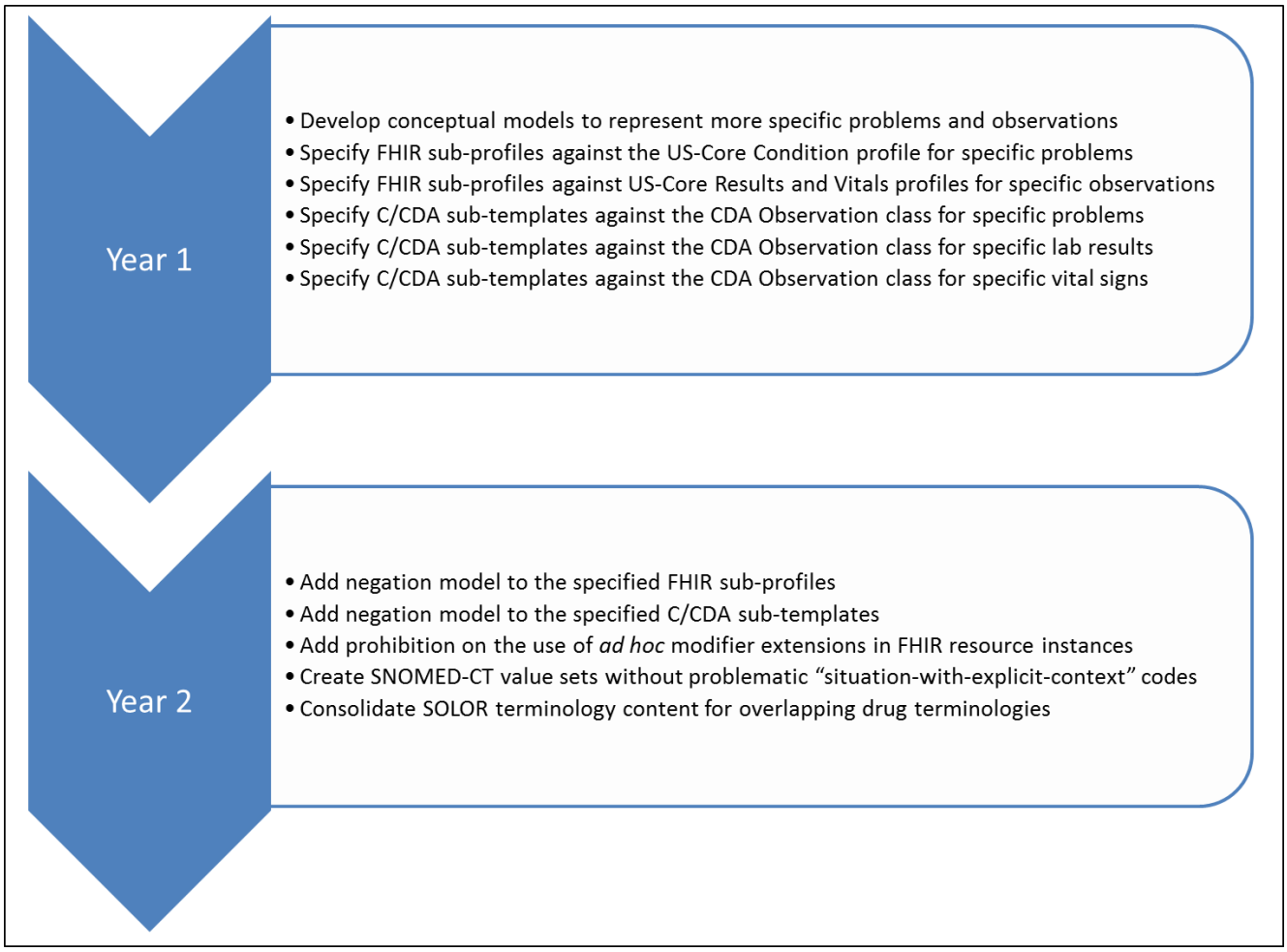
2 Overview of roadmap for the future-state architecture

The future state white paper for data modeling prescribes the creation of *more detailed clinical models* for FHIR profiles and C/CDA templates, the addition of *a formal model of negation* to those profiles and templates, *enhancements to terminology and value-set constraints* within the profiles and templates, and the *prohibition of ad hoc modifier extensions* to profiles and templates. The reader is strongly encouraged to review the future-state report to best understand the roadmap described here. Several key points, however, are summarized below.

- **More detailed clinical models**. The current data models for conditions and observations in FHIR profiles and C/CDA templates remain too generic, leading to variability on the part of different implementers when representing specific types of clinical conditions or observations. More detailed profiles and templates corresponding to specific types of clinical conditions and observations are needed to address this issue.
- **A formal model of negation**. Certain FHIR profiles and C/CDA templates provide multiple alternative and potentially conflicting ways of representing the absence or negation of a clinical condition or observation. Other FHIR profiles and C/CDA templates provide no way of representing absence and negation. A single formal model for representing negation in all applicable FHIR profiles and C/CDA templates is needed to address this issue.
- **Enhanced terminology and value-set constraints**. Certain value sets used in FHIR profiles and C/CDA templates also remain underspecified and allow redundant or semantically inconsistent codes to be used. As more detailed clinical models are created, it will present the opportunity to specify more constrained value sets for use within these profiles and templates, which will further reduce ambiguity and variability in the representation of specific clinical conditions and observations.
- **Prohibition on ad hoc modifier extensions**. FHIR profiles allow the addition of arbitrary, un-declared data elements to any patient data structure, some with the potential to change the meaning of the remaining, standardized data elements. This latitude creates the potential for important data to be misinterpreted or lost, and therefore must be prohibited.

Figure 1 summarizes the development roadmap for the future state, based on these concepts and other materials in the prior reports. Section 3 expands on each of the steps in the roadmap, with references to the corresponding sections of the future-state report (in square brackets at the beginning of each sub-section, such as “[4.3.1]”).

Figure 1. Overview of two-year roadmap.



3 Year-One Tasks

Year one will be devoted primarily to specifying more detailed FHIR profiles and C/CDA templates for clinical statements. These profiles and templates will be further refined in Year Two.

3.1 Develop conceptual models to represent more specific problems and observations

[2] Before more detailed FHIR profiles and C/CDA templates can be specified, more specific conceptual models are required for the problems and observations that will be represented. Similar work has been undertaken in related projects, such as CIMI and OpenEHR, and it's possible that portions of the models developed by those projects can be repurposed to develop the conceptual models for this project.

The year-one goals will focus on more specifically modeling problem-list entries ("problems") and certain types of observable measurements ("observations"). Specifically, conceptual models will be developed for at least the following types of clinical statement:

- Problems
    - Diagnosed disorders
    - Social history problems (e.g., homelessness, caregiver issues, substance abuse)
    - Family history problems (e.g., history of early onset heart disease, breast cancer)

    - Status post-procedure
- Observations
    - Laboratory results
        - Chemistry
        - Med Micro (culture results, antibiotic sensitivities)
        - Genomic
    - Vital signs

The conceptual models will define the data elements required to represent these various types of problems and observations, as well as characterize the specific value sets needed to populate those data elements that are coded. For example, the model for med-micro culture results may specify the subset of SNOMED-CT that covers just microorganisms and the subset of RxNorm that covers just antimicrobial agents.

When the conceptual models developed during this initial phase are mapped to FHIR profiles and C/CDA templates, certain of the specified data elements may already exist, whereas others will need to be added as extensions within the specific profiles and templates specified. Both FHIR and C/CDA allow the addition of extension data elements to profiles and templates.

3.2 Specify FHIR sub-profiles against the US-Core Condition profile for specific problems

[2.1 – 2.3] A FHIR profile already exists that presents a useful starting point for specifying more detailed "sub-profiles" to represent specific types of problems in problem lists. The US Core Condition profile[3], which was developed to support the U.S. meaningful-use program, has useful data-element constraints and value-set definitions that have been adopted by numerous implementers in the United States. Hence, this profile is an appropriate starting point for more specific sub-profiles. The FHIR profiling mechanism allows the creation of "derived" profiles[4] (sub-profiles) that are based, themselves, on existing profiles.

As an example of a sub-profile based on the HL7 US Core Condition profile, see https://simplifier.net/vakbs/us-core-condition-va. Although this profile does not specify a model for a specific type of problem, it does add extension elements to represent the provenance of the recorded data, as well as specifying more constrained value sets for certain data elements. It also incorporates features for formalized negation (as described in Section 4.1 below) and excludes certain problematic SNOMED-CT codes from the value set that may be used to encode the documented problem (as described in Section 4.4 below). Hence, it may be an appropriate profile upon which to base the more detailed sub-profiles prescribed here. Note that the HL7 profiling mechanism allows derived profiles (sub-profiles) to be specified to any level of profile depth. The FHIR sub-profiles for problem-list entries that are prescribed here could use this existing sub-profile as their "root" profile.

3.3 Specify FHIR sub-profiles against the US-Core Results and Vitals profiles for specific observations

[2.1 – 2.3] As with the envisioned FHIR profiles for problem-list entries, FHIR profiles also already exist that present useful starting points for specifying more detailed "sub-profiles" to represent specific types of lab results and vital signs. The US Core Results profile[5] and the US Core Vital Signs profile[6], respectively, provide useful data-element constraints and value-set definitions that have been adopted by numerous implementers in the United States.

Note also that a separate, more general, profile exists with respect to the FHIR base Observation profile that also adds extension data elements to represent the provenance of the recorded data, as well as incorporating formalized negation. Again, it may be useful to adopt parts of that profile (see

https://simplifier.net/vakbs/observation-va) for the newly created sub-profiles to confer those enhancements to them as well.

3.4 Specify C/CDA sub-templates against the CDA Observation class for specific problems

[2.1 – 2.3] The existing C/CDA template for transmitting problems[7] also lacks sufficient specificity for unambiguously representing problem-list entries. Hence, more specific "sub-templates" of this artifact should be developed, based on the conceptual models described in Section 3.1. The HL7 Clinical Document Architecture and the C/CDA implementation guide allow CDA-encoded data to specify conformance to multiple templates. This feature essentially allows the specification of "sub-templates" with respect to existing templates, provided that all valid instances of a sub-template also conform to the constraints of the base template.

The structure of the C/CDA template for problems is sufficiently generic that it can be further constrained to represent various types of problem list entries, including diagnosed disorders, social history problems, and status post-procedure conditions. Although alternative templates already exist for documenting social history and family history observations (e.g., see endnote 7, pages 402 and 496, respectively), these templates cannot be used within the Problem section of a C/CDA document. Hence, sub-templates of the problem-observation template must be created to represent social history and family history observations as problems. Fortunately, the structures of the social-history and family-history observation templates are sufficiently similar to the problem-observation template that the relevant information of the former can be represented within appropriately specified sub-templates of the latter.

3.5 Specify C/CDA sub-templates against the CDA Observation class for specific lab results

[2.1 – 2.3] The C/CDA implementation guide specifies only a single template to represent all test results, including all types of labs, as well as imaging results, functional-testing results, etc. (see endnote 7, p. 398). Given the variability in just the types of lab test that can be ordered and reported, this approach enables specific results to be structured and encoded in multiple different ways, compromising standardization and plug-and-play interoperability. Hence, as with the C/CDA problem-observation template, it is useful to specify sub-templates for different kinds of lab results based on the specific conceptual models for lab-result observations described in Section 3.1 (chemistry, med-micro, etc.).

Again, the HL7 Clinical Document Architecture and the C/CDA implementation guide allow the use of such sub-templates for specific types of lab results, provided that instances of the templates also conform to the general C/CDA template for result observations.

3.6 Specify C/CDA sub-templates against the CDA Observation class for specific vital signs

[2.1 – 2.3] As with test results, the C/CDA implementation guide specifies only a single template to represent all vital-sign observations (see endnote 7, p. 412). However, different vital signs may require different additional data elements and constrained value sets to be specified, such as the body position of a patient at the time her blood pressure was taken or the method by which a patient's heart rate was ascertained. In the absence of standardized data structures and value sets that are specific to particular vital-sign measurements, the same vital-sign data may get represented in multiple inconsistent ways, which compromises interoperability and, potentially, patient safety.

Hence, it is important to specify sub-templates of the base C/CDA vital-sign observation template to create tightly constrained and standardized representations for all relevant aspects of all vital-signs measurements.

4 Year-Two Tasks

Year two will focus on refining the FHIR profiles and C/CDA templates specified in year one.

4.1 Add negation model to the specified FHIR sub-profiles

[3.1 and 3.2] A prior whitepaper specified a formal model for negating clinical statements in a manner that is logically sound[8]. This formal model may be applied to the FHIR profiles created in year one through the addition of two data elements to each profile: *presenceIndicatorValue* and *presenceIndicatorScope*. PresenceIndicatorValue denotes whether a clinical statement is present, absent, or indeterminate. PresenceIndicatorScope denotes which specific parts of the clinical statement are affirmed, negated, or specified as indeterminate by the presenceIndicatorValue. Specifying the scope of the presenceIndicatorValue is critical to formally establishing the semantics of a clinical statement, particularly one that has been negated, because many data elements in FHIR profiles represent meta-data that is not intended to be negated. For example, FHIR profiles include meta data specifying the author of the clinical observation, which should remain affirmatively denoted even when the clinical observation is negated.

Two specific FHIR profiles, and corresponding example data, have been created to demonstrate the use of presenceIndicatorValue and presenceIndicatorScope to add negation to FHIR profiles. See https://simplifier.net/vakbs/us-core-condition-va and https://simplifier.net/vakbs/observation-va (and the corresponding documentation of the extension element *presence-indicator-extension* within these profiles).

4.2 Add negation model to the specified C/CDA sub-templates

[3.1 and 3.2] The formal model of negation previously specified can also be added to C/CDA templates, albeit with some additional restrictions and modifications, given the special constraints of the underlying Clinical Document Architecture (CDA) and Reference Information Model (RIM). Specifically, Release 2.0 of the CDA prohibits the addition of any extension data element to a CDA template that change the meaning of any standard data elements:

> "These extensions should not change the meaning of any of the standard data items, and receivers must be able to safely ignore these elements. Document recipients must be able to faithfully render the CDA document while ignoring extensions."[9]

Hence, the *modifier extensions* that may be added to FHIR profiles are not allowed when creating C/CDA templates. However, the standard RIM model on which the CDA is based allows the use of certain existing "negation indicator" data elements within any template that is based on the RIM classes "Act" and "Observation."[10] Specifically, these indicators comprise the actionNegationInd and the valueNegationInd data elements.

However, these built-in negation indicators are Boolean-typed data element that may take on only the values "true" and "false". Hence, specification of the "indeterminate" state, as included in the formal model of negation prescribed here, is not possible within C/CDA templates (only within FHIR profiles). Further, the CDA model also prohibits the addition of an extension element to denote the scope of negation, because such a data element could also change the meaning of standard data items (by specifying which ones are intended to be negated and which ones are not). Therefore, the formal model of negation will need to be adjusted when applied to C/CDA templates to support these restrictions of the CDA and RIM data models.

4.3 Add prohibition on the use of *ad hoc* modifier extensions in FHIR resource instances

[5.2] As mentioned, FHIR profiles may include modifier extensions that change the meaning of the overall clinical statement. This capability is useful and appropriate for formally denoting negation in instances of such profiles. However, the FHIR model also allows the *ad hoc* addition of modifier extensions to any FHIR data instances, even when such extensions are not defined as part of any profile. As discussed elsewhere[11], this capability can lead to adverse patient-safety issues and, hence, should be expressly prohibited as part of the FHIR profile specifications developed for this project. Such a prohibition should be clearly documented, and can be enforced by customizing FHIR validators to fail any FHIR profile instances that include *ad hoc* modifier extensions.

4.4 Create SNOMED-CT value sets without problematic "situation-with-explicit-context" codes

[4.1] A number of existing value sets referenced by FHIR US-Core profiles and C/CDA templates include SNOMED-CT codes from both the SNOMED-CT *Clinical Finding* hierarchy (rooted at the SCT code 404684003) and the *Situation with Explicit Context* hierarchy (rooted at the SCT code 243796009). The latter hierarchy allows the representation of concepts that include "context" qualifiers, such as qualifiers that negate findings, qualifiers that ascribe findings to a patient's family members, and qualifiers that indicate whether the findings are currently present or were present in the past. As discussed elsewhere[12], allowing certain such context qualifiers can lead to redundancies within value sets, as well as incorrect negation semantics.

Where value sets that allow any code from the SNOMED-CT *Situation with Explicit Context* hierarchy are used within FHIR profiles and C/CDA templates, they should be replaced with more constrained value sets that prohibit the problematic codes from the *Situation with Explicit Context* hierarchy. For example, when used to code patient problems (i.e., within sub-profiles of the FHIR US Core Condition profile and sub-templates of the C/CDA Problem Observation template), the applicable value set should exclude SNOMED-CT codes that specify the negation of a clinical finding (which leads to semantic inconsistencies) and that specify the presence of a clinical finding in the patient at the current time (which lead to redundancies with respect to codes in the SNOMED-CT *Clinical Finding* hierarchy. An example of such a value set has been defined and may be accessed at https://simplifier.net/vakbs/us-core-problem-va. Note that this value set still allows certain codes from the SNOMED-CT *Situation with Explicit Context* hierarchy to be used, for example SCT 431330007 ("Family history of BRCA1 gene mutation") and SCT 161456009 ("History of Iron Deficiency Anemia"), because these codes do not lead to semantic inconsistencies and coding redundancies when used to represent items on a patient's problem list.

4.5 Consolidate SOLOR terminology content for overlapping drug terminologies

[4.2] A principal envisioned benefit of the SOLOR project is to integrate coded concepts from distinct terminologies so as to formally reconcile semantic equivalences and other logical relationships across the terminologies' content[13]. Such reconciliation enables patient data that have been encoded using different terminologies to be more accurately transferred between clinical information systems and more effectively analyzed when integrated within population-health data repositories.

The integration of terminology resources within SOLOR can also facilitate the creation of value sets for FHIR profiles and C/CDA templates when the contents of such value sets must be drawn from multiple terminologies. A notable example of this requirement is in the value sets for encoding allergenic substances in the FHIR US-Core *AllergyIntolerance* profile[14] and the C/CDA *Allergy-Intolerance Observation* template[15]. As discussed earlier[16], these value sets include overlapping content from SNOMED-CT, RxNorm, NDF-RT, and (in the case of the C/CDA) the set of Unique Ingredient Identifier

(UNII) codes. To correctly analyze allergen codes drawn from this expansive value set (for example, in decision-support rules or quality measures), the recipients of FHIR and C/CDA data must have access to a resource that represents and manages the semantic relationships across the contents of all of these terminologies.

SOLOR has the opportunity to be this resource by integrating the contents of SNOMED-CT, RxNorm, NDF-RT, and UNII in a semantically sound way and making the integrated content available to any recipients of patient data encoded using relevant FHIR profiles and C/CDA templates. The existing values sets used in the *AllergyIntolerance* profile and the C/CDA *Allergy-Intolerance Observation* template would, thereby, reference the integrated drug contents of SOLOR, enabling recipients of FHIR-encoded and C/CDA-encoded data to more soundly use such data. The creation of such a SOLOR resource would, therefore, be an apt demonstration of SOLOR's power and utility.

5 Conclusion

The VA can begin addressing the patient-safety issues inherent in the current design of the US Core FHIR resources and the C/CDA templates within the two-year time frame described in this whitepaper. The creation of more detailed clinical models for specific conditions and observations and the instantiation of these models as more FHIR sub-profiles and C/CDA sub-templates will reduce the substantial variability of patient-data representation that current FHIR profiles and C/CDA templates allow. Additional constraints on the manner in which clinical statements are negated, value sets are managed, and extension elements are allowed will further standardize the way that clinical data are represented, reducing the potential for crucial components of transferred patient data structures to be misinterpreted or lost. These enhancements to FHIR resources and C/CDA templates will materially improve patient safety as their use in daily medical practice continues to grow.

References

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