National Institute of Standards and Technology • U.S. Department of Commerce

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Templated CDA: Key Concept for Interoperability

Lantana Consulting Group

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By
Lantana Consulting Group

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Executive Summary

This document supplements information about "templated CDA" in the context of the Healthcare Information Technology (HIT) Standards Analysis Project carried out by Lantana Consulting Group for the National Institute of Standards and Technology (NIST).

As part of our HIT Standards Analysis and our goal to move towards more testable interoperability standards, we frequently assert in the various reports prepared under this contract that **an architecture based on model-driven standards (i.e., standards derived from formal and computable models) enable far more robust testing strategies than we have in use today**. The key model-driven technology is one underlying the Continuity of Care Document (CCD) and other Health Level Seven (HL7) Clinical Document Architecture (CDA) implementation guides known as "templated CDA". This document lays out the key concepts of templated CDA to help the reader weigh the assertions and recommendations we have made throughout our reports. Templated CDA touches all aspects of interoperability. From the perspective of test and validation, this is critical as it provides an organic, single, and structured source for the deployment of structured information exchange.

Such a comprehensive approach is critical for large scale, rapid adoption because a modest initial investment leverages the templated approach to achieve large-scale, cost-effective extensibility. It gives implementers a roadmap for test validation so that they can interpret narrowly targeted interoperability goals within a wider context and using a consistent tool set.

This document's Introduction begins by laying out the business case for CDA and for templated CDA. The next section on CDA Templates: Model-driven Computable Objects presents a high-level technical overview and discusses how CDA templates streamline both standards development and standards implementation. Templated CDA for Standards Development and Harmonization provides data on the growing use of CDA templates, and the growing reuse across CDA implementation guides. Templated CDA for Information Capture, Reuse, and Analysis describes how CDA templates drive greater consistency in data capture and data representation, leading to greater capabilities for comparative effectiveness and retrospective analyses. A Templated CDA Interoperability Roadmap lays out a concrete set of steps that support an incremental path to

semantic interoperability based on CDA and templated CDA. The appendix on Templated CDA Use Case: NHLB presents a more detailed scenario, illustrating how CDA templates might be used in practice to achieve our ultimate objective of improving patient care.

Introduction

Clinicians all over the country capture patient data through their method of choice—a voice interface, keyboard, or menu-driven interface. The user interface is customized to their preferences for sequence and naming conventions and includes prompts or fields for all the customary elements. What if the prompts ensured that the same basic information was captured via all modalities in all venues and that, once captured, could be shared with clinicians across the country? And what if the underlying encoding was transparent to all EHRs and supported clinical trials, comparative effectiveness and all manner of secondary use?

What if the interface also prompted clinicians for missing data required to complete a quality measure or public health report?

If we could do this with minimal disruption to current clinical workflow while maximizing test and validation, the country would be well launched on an incremental path to semantic interoperability—the path to Meaningful Use. In this paper, we describe how a library of CDA templates can meet many of the evolving interoperability and testing requirements in the United States.

Health Level 7 (HL7) Clinical Document Architecture, Release 2 (CDA) is an American National Standards Institute (ANSI) accredited standard specification for the representation of clinical documents (such as Discharge Summary, Diagnostic Imaging Report, Operative Report, and Progress Note). Based on Extensible Markup Language (XML), CDA is a document markup standard that specifies the structure and semantics of clinical documents for the purpose of information exchange. A CDA document is a defined and complete information object that can exist outside of a message and can include text, images, sounds, and other multimedia content[1]. Any tool that works with clinical information—an electronic medical record (EMR), clinical information system, or transcription system—can produce CDA; in fact, you can create a CDA with a word processor or XML editor.

CDA's features:

Consistency. There is a single specification (and single XML schema) for all CDA documents.

Stability. CDA has been a normative ANSI standard since 2000. Release 2 has been integrated into production applications since its release in 2005.

Consensus driven. CDA was developed by volunteers and balloted through HL7's consensus process, drawing input from hundreds of organizations, large and small, from over a dozen countries.

Extensibility. CDA templates allow incremental expansion to meet new use cases while avoiding proliferation of incompatible extensions.

Broad implementation experience. CDA is widely implemented across the globe[2].

1 *HL7 Standard: Clinical Document Architecture, Release 2 (CDA*). ANSI-approved HL7 Standard; May 2005.

2 See these web sites, which reference a sampling of CDA implementations: http://tinyurl.com/cda-around-the-world, http://www.showmeyourcda.net/

Gentle on-ramp to information exchange. CDA is straightforward to implement. It provides a mechanism for "incremental semantic interoperability" beginning with a simple, universally accessible and readable narrative and adding interoperable coded data over time based on local and national priorities.

Why are templates needed to achieve consistent capture and validation? Imagine wanting to communicate information about diabetes. Not only is there a wide range of representations (e.g., different codes, different interoperability profiles), there is a wide range of ways to describe exactly which representation to use in a given scenario. Organizations create local implementation guides as paper documents, as various types of electronic profiles, et cetera. The variability in the ways in which constraints or profiles are asserted, coupled with the wide range of representations, makes it almost impossible to determine what the alternatives are when wanting to communicate information about diabetes. CDA templates, in contrast, are structured, patterned representations, in a common formalism.

The templates are modular, reusable building blocks, layered on top of the base CDA standard. The templates enable the semantic representation of a wide variety of data elements, under a wide variety of scenarios. As model-driven computable objects, they can be manipulated via a wide variety of automated processes. For example, standards developers can search a library of CDA templates to support template reuse, harmonization, and test.

The audience for templated CDA can be divided roughly into standards developers (includes profilers, regulators, et cetera) and implementers. The rationale and business case for the use of templates differs by audience, addressing the needs of both, as follows:

Streamlined standards development. A building-block approach that reuses templates, where new standards only have to create additional needed templates, supports more rapid, robust, and cost-effective standards development.

Streamlined standards implementation. A building-block approach that reuses templates across a variety of CDA implementation guides leads to a more rapid and less expensive test and deployment.

Reuse. CDA templates (for example blood pressure, discharge diagnosis, and active problems) can be thought of as atomic clinical statements, built for reuse. They can be repackaged with other templates in any number of CDA implementation guides.

CDA's "incremental interoperability" strategy. As noted above, a minimally conformant CDA document is easy to construct. Building on the minimum, Stage 1 Meaningful Use requires adoption of a limited number of CDA templates to construct a valid Health Information Technology Standards Panel, HITSP/C32 instance. Stages 2 and 3 of Meaningful Use will likely recommend adoption of additional templates.

Built on open standards. CDA templates are application independent and do not require a novel or proprietary syntax.

Built on experience with data element repositories. Data element repositories such as the Agency for Healthcare Research and Quality's (AHRQ) United States Health Information Knowledgebase (USHIK)[3] and the National Cancer Institute's (NCI) Cancer Data Standards Registry and Repository (caDSR)[4] are based on the International Organization for Standardization (ISO) 11179 data element model. Advances in semantic interoperability in such areas as vocabulary binding and safe context, have led to the enhancements embodied in the underlying formal representation of CDA templates.

3 http://ushik.ahrq.gov/

4 https://cabig.nci.nih.gov/concepts/caDSR/

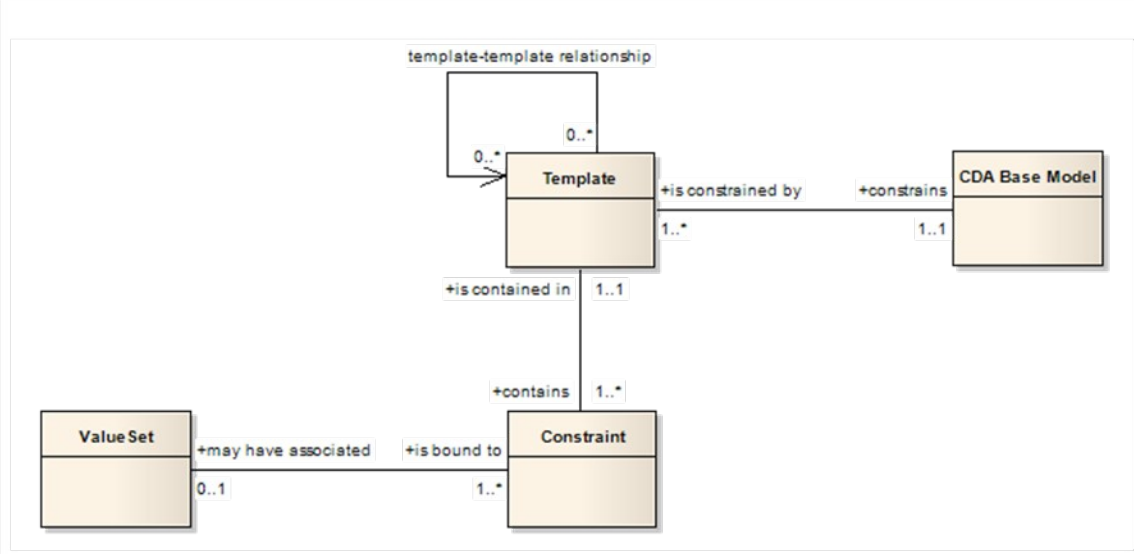
A template, here, is a named set of formal, computable constraints on the base CDA standard. CDA document types can be constrained through the application of one or more templates to meet a need for a particular type of clinical document.

Templates, drawn from a library of reusable templates, can be assembled into various kinds of implementation guides according to use case. A set of templates collected in a CDA implementation guide details the machine processable representation of the underlying business requirements. Professional society recommendations, national clinical practice guidelines, and standardized data sets can be expressed as CDA templates.

Many kinds of templates can be created. The most relevant are: (1) those that represent individual data elements (**CDA entry-level templates**); (2) those that represent document sections (**CDA section-level templates**); (3) those that represent documents (**CDA document-level templates**); and (4) those that constrain the document-level metadata in the CDA header (**CDA header templates**).

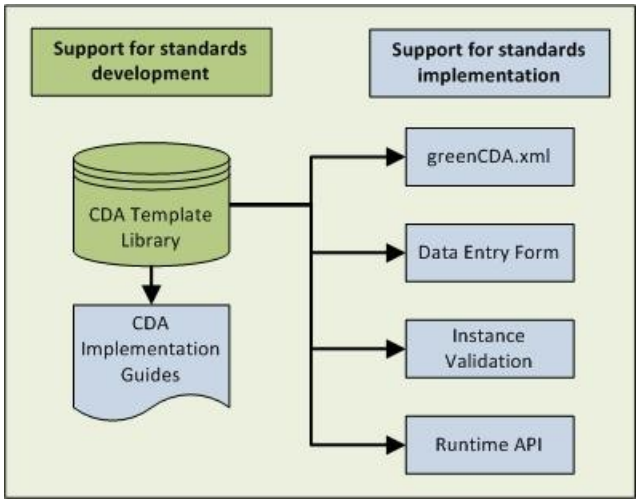
As noted above, a template is a named set of constraints on the base CDA standard (see the figure Template relationships and constraints). Templates can relate to other templates through containment or specialization relationships. The constraints typically restrict the cardinality of a CDA field or restrict the allowable values within a CDA field. In many cases, a constraint may bind the CDA field to a value set (a list of allowed codes).

Figure 1: Template relationships and constraints



CDA templates are model-driven computable objects that can be stored in a database that functions as a CDA template library. Such template libraries support both standards development and implementation.

Figure 2: CDA template library supporting standards development and implementation



Template library functions:

Quality assurance. CDA templates can be tested to ensure that they are built correctly.

Discoverability. CDA templates allow searches via template metadata, template structure, and semantics, including value sets.

Vocabulary binding. CDA templates adhere to the latest HL7 recommendations for vocabulary binding.

Management. CDA templates have formal relationships to one another (e.g., containment and specialization relationships) supporting template management.

Consistency. CDA templates can be tested for consistency with corresponding HL7 Version 3 domain models.

Template library outputs:

CDA implementation guides. Libraries export templates that are aggregated into CDA implementation guides.

CDA instance validation. Model-driven libraries generate CDA instance validation rules (e.g., Schematron or other modalities).

Runtime application programming interface. CDA templates can be transformed into source code (e.g., JAVA, .NET) to support the programmatic creation and/or parsing and/or validation of CDA document instances.

greenCDA XML. CDA templates can generate small, implementation-specific XML schemas, following the principals described in *HL7 Implementation Guide for CDA Release 2: **greenCDA**, Release 1*. The **greenCDA** philosophy is to collapse everything for a particular use case into a simple XML schema to streamline instance creation, parsing, and validation. The simplified XML has clinically meaningful element and attribute names, is 100% transformable into canonical CDA, and hides certain CDA complexities (such as fixed attributes). As such, it is easy to implement and can be automatically transformed into canonical CDA to meet robust processing requirements.

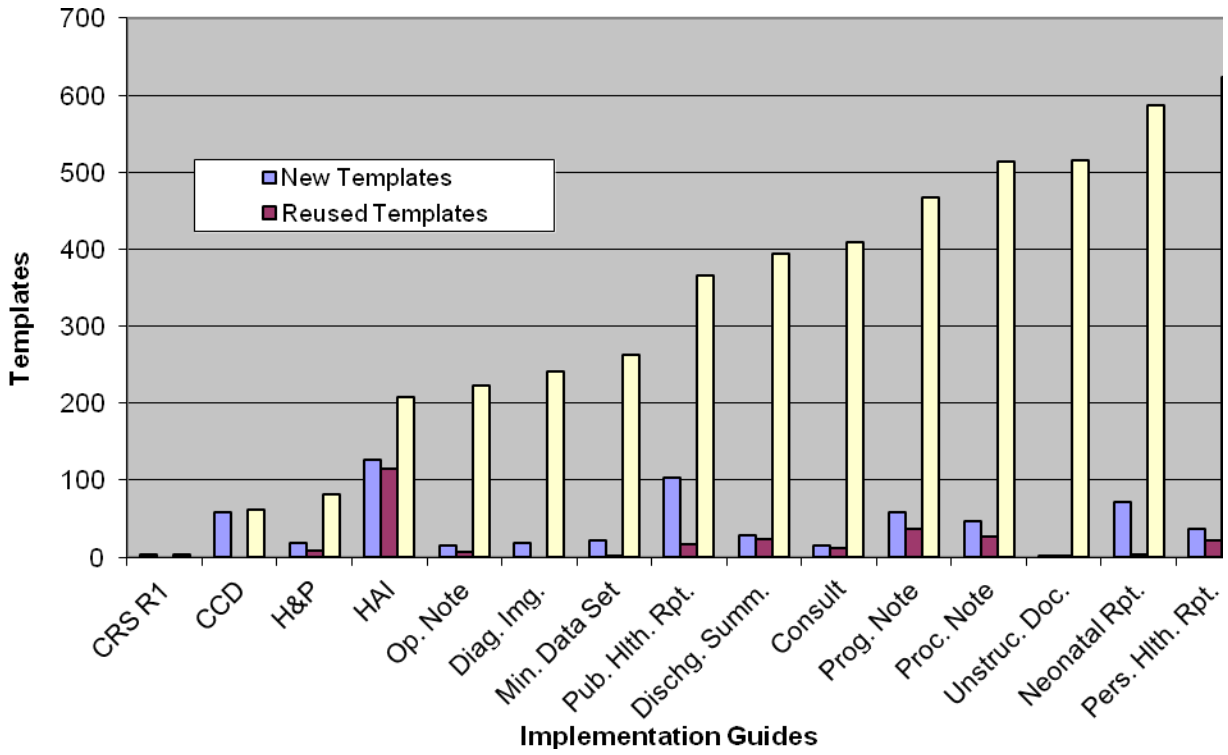
Data entry form. CDA templates can drive data entry. (For an example, see the appendix Templated CDA Use Case: NHLBI).

Templates reduce the level of effort in developing a standard by providing ready-made and consistent patterns on which to build. In some cases, standards developers may satisfy a use case requirement through minor changes to existing templates or, better yet, by recombining existing templates into new packages that address the requirement without additional modeling.

In the US, this process is already well established. The first set of formal templates for CDA was developed for CCD in 2007[5]. Since then, the syntax and formalism for templates has evolved in minor ways, and the original CCD templates have been reused by Integrating the Healthcare Enterprise (IHE), the Health Story Project, and HITSP, and within virtually all subsequent HL7 implementation guides.

The next figure illustrates the growth and reuse of CDA templates across standards via a sampling of CDA implementation guides balloted through HL7 over the past few years.

Figure 3: Template proliferation in CDA implementation guides



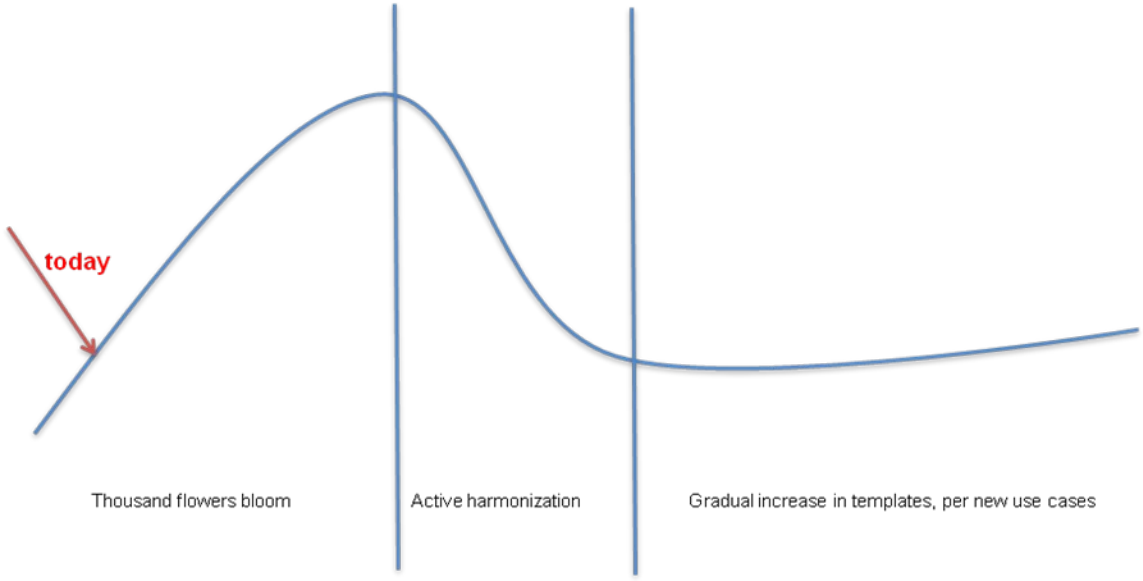
In this figure, the horizontal axis is roughly chronologic and shows that, as new guides are developed, a significant number of templates are reused from existing guides. The first guide, Care Record Summary (CRS), contains no formal templates; CCD contains fewer than 100

5 *CCD: Continuity of Care Document (CCD) ASTM/HL7*. http://www.hl7.org/documentcenter/ballots/2007JAN/downloads/CDAR2_IMPL_CCD_I2_2007JAN.zip

templates. The balloted HL7 guides tallied here have 623 unique templates or, on average, 42 templates per guide, 24 new, and 18 reused.

Over time, we anticipate that the number of CDA templates will continue to grow—a thousand flowers will bloom as more organizations create and adapt templates to their own requirements. During the past four years, IHE and HITSP have contributed significantly to the available pool. With freely flowering template proliferation, inevitably some duplication and incongruities will occur. We expect the number of templates to expand rapidly and then decrease through harmonization and consolidation of requirements. The next figure illustrates a potential evolution to stable template growth and adoption.

Figure 4: Evolution to stable growth of templates



Harmonization without a common basis and formal representation could easily become an intractable problem, particularly where requirements cover a range of stakeholders, in various formats, in different repositories, in different organizations, et cetera. With all players on board for templated CDA, harmonization is already underway via projects such as the HL7/IHE Health Story Consolidation Project[6] under the auspices of the Office of National Coordinator (ONC) Standards and Interoperability (S&I) Framework.

Templated CDA for Information Capture, Reuse, and Analysis

This section illustrates several advantages templated CDA provides in various stages of the information lifecycle.

1.1 Information Capture and Analysis

We started this paper asking you to imagine that providers across the country captured data in a consistent manner. Such a picture would represent major progress compared with the status quo, where providers may not capture the same information and, when they do, may make the same assessment yet capture the data in myriad forms. For example, one provider captures "drinks per

6 http://jira.siframework.org/wiki/display/SIF/CDA+Consolidation+Project

day" whereas another provider captures "ounces of wine, beer, or hard liquor per week". Similarly, providers capture data elements with different timestamps (e.g., "recently", "in the past month", "since January", and so on), and providers are given different selection lists to capture clinical data (e.g., one provider can select "disorder of bilirubin metabolism" whereas another provider can select the more specific "Gilbert's syndrome" or "Crigler-Najjar syndrome").

Much of this variability can be addressed as template compliance is pushed up the information "food chain" to influence data capture. The templates themselves provide the means to do so. Any data capture tool can be constrained by the requirements of a template. Some applications go further, instantiating a direct relationship between template and data entry form. NCI is developing a system to drive data capture for clinical trials from a library of CDA templates; IBM demonstrated the same basic functionality for public health at Healthcare Information and Management Systems Society (HIMSS) 2010[7].

At minimum, template specifications clearly delineate data capture requirements and provide the means to validate compliance through automated processes. Various validation methods are feasible[8], ranging from XML schema language to compiled XML Path Language (XPath) statements (Schematron) to programming languages such as Java or .NET.

While the gold standard for data analysis is data captured under a strict collection protocol, where patients have been randomly assigned to different treatments, **data captured in accordance with CDA templates are more consistent, leading to greater capabilities for comparative effectiveness and retrospective analyses.**

1.2 Information Reuse

Stage 1 Meaningful Use criteria require generation of a HITSP/C32 instance containing standardized problems, medications, lab results, et cetera. Certified electronic health records (EHRs) can create and convey instance data in this standardized way. It follows that EHRs can then respond to quality measure criteria and decision support rules expressed in a similarly standardized manner. **To the extent that an EHR can instantiate a CDA template, that EHR can process a corresponding quality measure criterion and decision support rule**.

This vision of coupling quality reporting and shareable decision support to an EHR interface defined by CDA templates is far from theoretical. It is the basis for the eMeasure development work done by HITSP and by the National Quality Forum (NQF). That project aligns NQF's Health Information Technology Expert Panel (HITEP) Quality Data Elements (QDE) with CDA templates, reusing them as eMeasure building blocks.

The majority of implementations prefer to use existing, localized schemas rather than rip-and-replace to achieve standards compliance. **The templated CDA vision for an interoperability infrastructure has a CDA template library at its foundation that provides a virtual interface between the external, standards-based exchanges, and the localized data store.** Templates in the library define a standard interface. Via this interface, the EHR can (1) generate

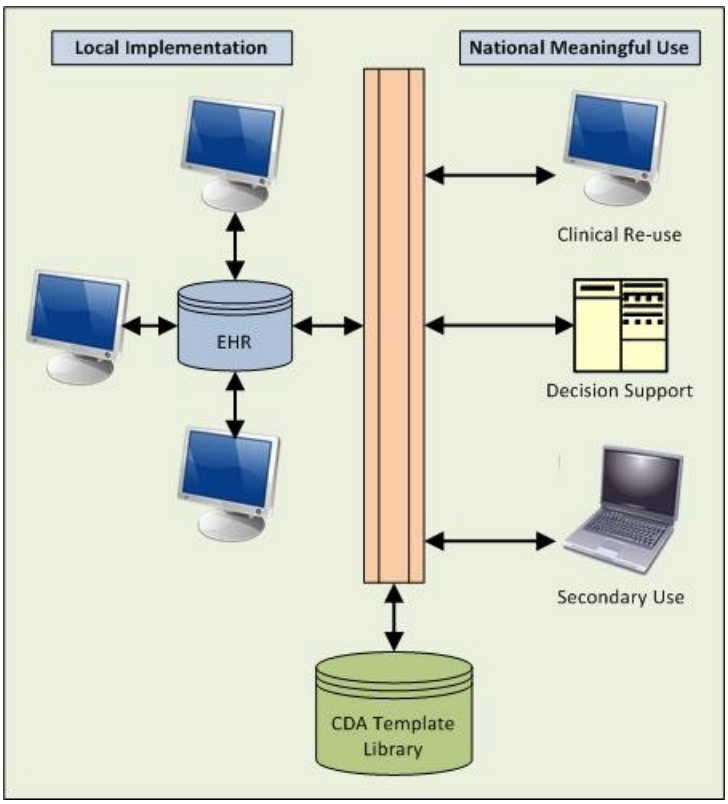
7 Renly, S., Demonstration of XForms and IHE RFD for Public Health Case Report (PHCR) Influenza, HIMSS Interoperability Showcase, March 2010.

8 The advantages and limitations of various approaches is the subject of a companion paper on CCD definition: "Continuity of Care Document (CCD) Coverage Report", May 2011.

many types of CDA documents, (2) interpret quality measure criteria, and (3) interpret decision support rules.

Simply stated, and illustrated in the next figure, an EHR's standard interface approximates those CDA templates that the EHR can instantiate.

Figure 5: EHR interface defined by the CDA templates it supports

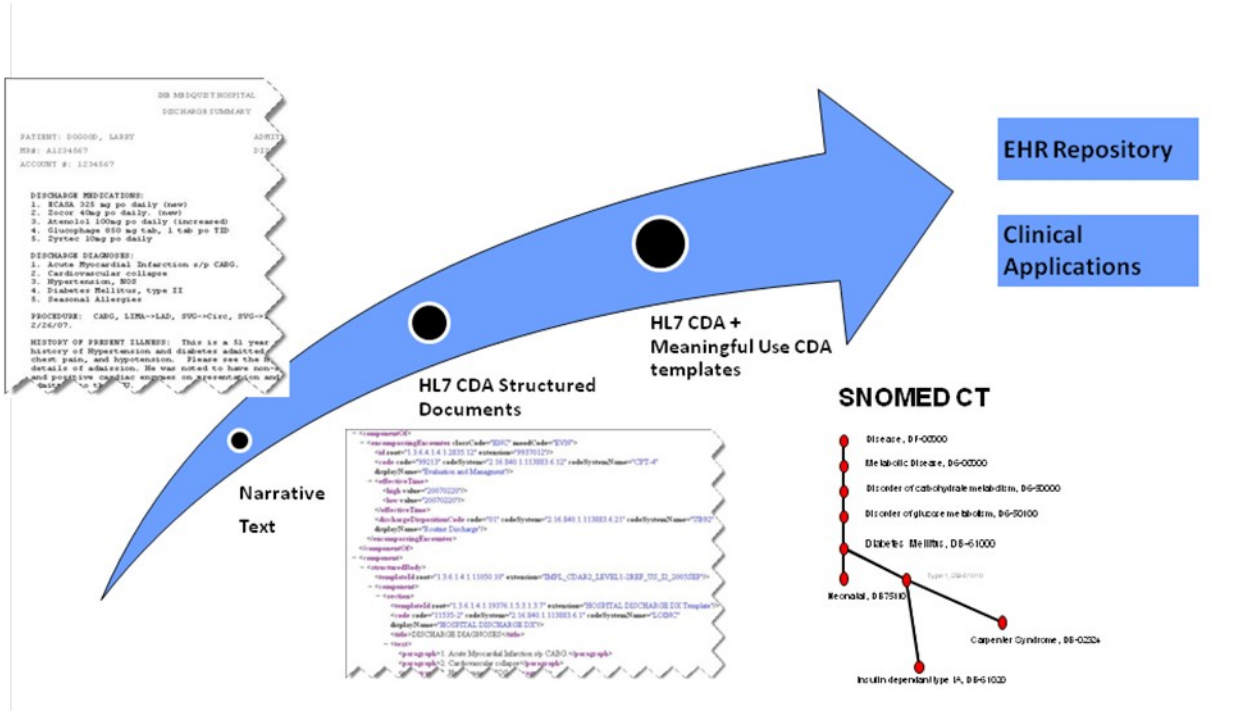


A Templated CDA Interoperability Roadmap

Templated CDA **creates minimal disruption to current clinical workflow while putting you on an incremental path to semantic interoperability—a path that leads to Meaningful Use**.

Our roadmap begins with minimally conformant CDA documents. Such documents are easy for clinical document applications to produce, deliver immediate value to point-of-care clinicians, and lay out a high-level structure for common clinical documents such as Discharge Summary, Diagnostic Imaging Report, Operative Report, and Progress Note. From there, we envision adoption of templates in a staged and incremental fashion, largely directed by Meaningful Use stages, as illustrated in the next figure.

Figure 6: Incremental adoption of CDA templates



Building upon this incremental strategy, our roadmap describes key activities needed to drive towards a more testable semantic interoperability infrastructure over the next two to three years.

2011 activities:

Template tooling. The capabilities described above (see CDA Templates: Model-driven Computable Objects) are real; however, we expect the tooling, including a variety of automated and semi-automated processes, to be greatly improved in the near future.

CDA "simplification". **greenCDA** technology will streamline instance creation, parsing, and validation while maintaining the common basis required for semantic interoperability.

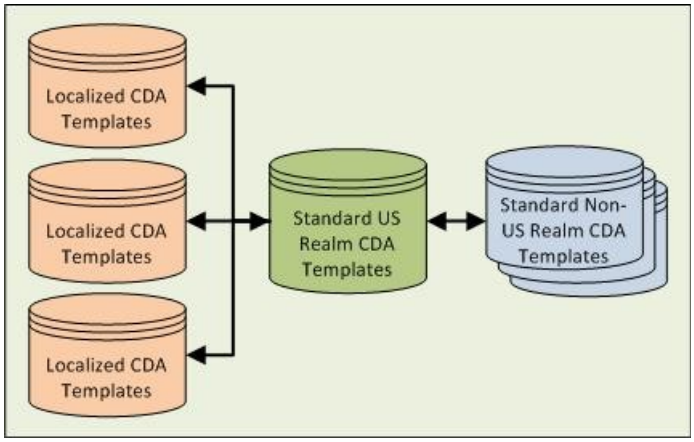
Template harmonization. Template harmonization activities have begun, such as those through the ONC-sponsored HL7/IHE/Health Story CDA Implementation Guide Consolidation Project[9]. Harmonization begins to encompass claim attachments for adjudicating reimbursement claims.

Template exchange. A template exchange formalism that allows sharing CDA templates across tools and across libraries will be developed.

Templates expand for reuse. The current National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) reporting, a national, templated-CDA initiative is instantiated as a model for reporting public health, quality, and research data.

Figure 7: Template exchange across libraries

9 http://wiki.siframework.org/CDA+Harmonization+WG



2012 activities:

Template tooling. We expect further enhancement of the template tooling, making development and implementation of templates much easier compared to current capabilities and further uptake by a variety of vendors and open source projects.

Template harmonization. We expect HL7, IHE, and/or ONC to work on new template harmonization projects. The template library supports rulemaking on claims attachments.

Template prioritization. Templates developed under the ONC-sponsored HL7/IHE/Health Story CDA Implementation Guide Consolidation Project are likely candidates for Stage 2 Meaningful Use, and, if so adopted, will establish a bedrock of EHR capabilities for the exchange of common clinical documents (e.g., Discharge Summary, Diagnostic Imaging Report, Operative Report, and Progress Note).

CDA Release 3. With growing adoption of CDA, we anticipate an increased number of requirements that push the envelope of CDA Release 2. CDA Release 3 will have a richer underlying data model, which will support the development of a larger set of templates.

Cohesion across domain model formalisms. Growing interest in technologies similar to templated CDA and a growing interest in international harmonization will lead to a comparison of templates, "archetypes"[10], "detailed clinical models"[11], "domain analysis models"[12], and "clinical element models"[13], along with a process for mapping subject-matter expertise captured via many of these formalisms into CDA templates.

2013 and ongoing activities:

Template tooling. Ongoing enhancement of template tooling.

Template harmonization. New template harmonization projects.

Template prioritization. Ongoing prioritization.

Template migration. Some templates written for CDA Release 2 will be revised to better use the richer semantics in CDA Release 3.

10 http://www.openehr.org/116-OE.html; http://esearch.cen.eu/Details.aspx?id=3704020

11 http://wiki.hl7.org/index.php?title=Detailed_Clinical_Models

12 http://wiki.hl7.org/index.php?title=Domain_Analysis_Model

13 http://intermountainhealthcare.org/cem/

Conclusion

In this document, we have provided supplemental background information and details on templated CDA.

A templated-CDA strategy streamlines standards development, standards implementation, and standards-based test and validation. As a result, we are seeing growing adoption of this approach across both standards development and standards recognizing bodies.

Templated CDA is a key technology underlying CCD and other HL7 CDA implementation guides. As formal computable objects, CDA templates enable far more and more robust HIT interoperability standards testing strategies than we have in use today.

This model-based architecture provides the critical context, on-ramp, and roadmap so that Meaningful Use can target specific objectives without compromise to the broad goals of interoperability.

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United States Health Information Knowledgebase (USHIK) http://ushik.ahrq.gov/

"Where in the World is XDS and CDA" Google Map. http://tinyurl.com/cda-around-the-world

APPENDIX A — ACRONYMS AND ABBREVIATIONS

AHRQ	Agency for Healthcare Research and Quality
ANSI	American National Standards Institute
caDSR	Cancer Data Standards Registry and Repository
CCD	Continuity of Care Document
CDA	Clinical Document Architecture
CRS	Care Record Summary
EHR	electronic health record
EMR	electronic medical record
HIMSS	Healthcare Information and Management Systems Society
HIT	Health information technology
HITEP	Health Information Technology Expert Panel
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
IHE	Integrating the Healthcare Enterprise
ISO	International Organization for Standardization
NCI	National Cancer Institute
NIST	National Institute of Standards and Technology
NHLBI	National Heart, Lung, and Blood Institute's
NQF	National Quality Forum
ONC	Office of National Coordinator
QDE	Quality Data Elements
S&I	Standards and Interoperability
USHIK	United States Health Information Knowledgebase
XML	Extensible Markup Language
XPath	XML Path Language

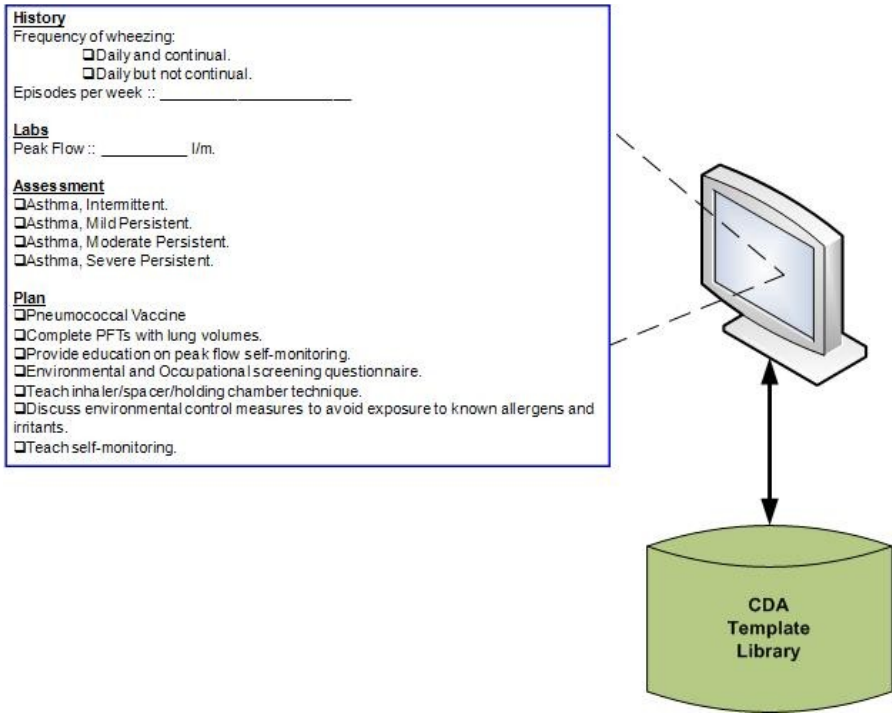
APPENDIX B — TEMPLATED CDA USE CASE: NHLBI

The following scenario, based on the National Heart, Lung, and Blood Institute's (NHLBI) Guidelines for the Diagnosis and Management of Asthma, illustrates templated CDA. In this scenario, the objective is to integrate the NHLBI guidelines directly into the process of care via the construction of a corresponding data entry form, thereby making it easier to provide optimal patient care.

Domain experts review the NHLBI guideline and construct a number of CDA templates. CDA entry-level templates include "frequency of wheezing observation", "wheezing episodes per week observation", "peak flow measurement observation", "pneumococcal vaccine recommendation", "asthma severity assessment", et cetera. CDA section-level templates include "history section", "lab section", "assessment section", and "plan section". Together, they create a single document-level "NHLBI Asthma Management Progress Note" template.

The templates, which are formal and testable constraints on the base CDA specification, are transformable into a data-entry form, as shown in the next figure.

Figure 8: Template constraints expressed in data-entry form



The next figure shows that, upon completion of data-form entry, a corresponding CDA instance is generated. This instance validates against the base CDA standard and against asserted templates.

Figure 9: Generation of templated CDA instance from data-entry form