Canada Health Infoway | Inforoute Santé du Canada

Pan-Canadian Clinical Document Architecture (CDA) Guidance Paper

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Canada Health Infoway | Inforoute Santé du Canada

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A number of The Ringholm Whitepapers are referenced and/or quoted within this document - http://www.ringholm.com/en/whitepapers.htm Calvin Beebe's CDA Primer & Blog were used as sources of content - http://webpages.charter.net/calvinbeebe/CDA-QA/archives/-hl7-general/index.html

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Purpose

The purpose of this document is to provide guidance on the use of **Health Level 7 Clinical Document Architecture Release 2** (HL7 CDA R2) for use within Canadian projects. This guidance document is meant to be read in conjunction with the ***pan-Canadian CDA Header Implementation Guide*** in order to understand the complete CDA R2 specification as it relates to deployment in the Canadian environment. This document is **not** meant as an HL7 CDA R2 training document.

Health Level 7 Clinical Document Architecture Release 2 (HL7 CDA R2) Standard: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

CDA Defined

Health Level 7 (HL7), Clinical Document Architecture (CDA) is a standard for representing clinical document content when exchanging data between systems. CDA uses XML markup language to represent clinical documents and all HL7 CDA R2 documents share the following characteristics:

Persistence – A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements (**NOTE:** There is a distinct scope of persistence for a clinical document, independent of the persistence of any XML-encoded CDA document instance).

Stewardship – A clinical document is maintained by an organization entrusted with its care.

Potential for authentication - A clinical document is an assemblage of information that is intended to be legally authenticated. The information in a CDA document has the potential to be legally authenticated.

Context - A clinical document establishes the default context for its contents. The document should establish who, what, when, where, and why, so the decisions made are in the best interest of the patient.

Wholeness - Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document. Taking a portion of a clinical document's narrative out of context is discouraged because the authentication spans the whole of the document.

Human readability – A clinical document is human readable. This ensures the legal authenticators view of the document is shared downstream with other care providers.

Audience

The audiences for this guidance paper are the architects and developers of healthcare information technology (HIT) systems in the Canadian Realm that exchange patient clinical data.

It could also be of interest to business analysts and clinical managers who could benefit from a basic guidance on the use of Clinical Document Architecture (CDA) for exchanging clinical documents between care settings and care providers.

This document assumes the reader is familiar with CDA concepts found in the CDA Release 2, 2005 Normative Standard. In addition, the reader should be familiar with the relationship between the HL7 CDA Standard and IHE technical frameworks and profiles. Finally, many components of the document are influenced by the HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1 – US Realm.

Scope

The scope of this document is based on topics of interest expressed at Spring Partnership 2012 during discussions on HL7 CDA use in Canada. These topics were vetted with Canadian stakeholders via the Standards Collaborative (SC). The document is meant to complement and provide additional details on many of the topics covered in the normative CDA R2 Standard which are required for a consistent, pan-Canadian approach to the delivery of CDA specifications.

The document is not meant to be a training document for CDA R2. It is meant to provide a common level of understanding on a number of subject areas within the CDA R2 Standard. Whenever possible, the document will strive to make recommendation on subject areas that are of interest to Canadian projects.

Recommendation Summary

This is a summary of recommendations contained in this document. Further details on each are found in the sections of the document from where the recommendation is derived.

Recommendation 1*: Apply constraints to the CDA R2 normative specification within the Canadian Realm (pan-Canadian CDA Header, and Canadian document templates*).

Recommendation 2; *Reuse/refactor templates (document, section, entry level) from other implementation guides when possible.*

Recommendation 3: *When using CDA to represent data already defined with the Pan-Canadian HL7 V3 Messages, use CDA section entries to convey this data.*

Recommendation 4: *One size does not fit all. Evaluate the best exchange paradigm (messaging or document) for each information sharing requirement.*

Recommendation 5: *To achieve consistency in CDA implementations follow the CDA R2 standard per the HL7 specification and the pan-Canadian CDA Header Implementation Guide.*

Recommendation 6: *Extensions to the CDA R2 schema should be optional and brought forth to the Infoway Standards Collaborative to be promoted nationally and/or vetted with the HL7/IHE community.*

Recommendation 7*: Use templates to constrain the CDA R2 Standard for specific use cases. This document recommends a future project establish a set of pan-Canadian templates based on "common" use cases for use within the pan-Canadian CDA Header Implementation Guide.*

Recommendation 8: *This document recommends that all templates (open or closed) should be included within the CDA section of InfoCentral or a registry and managed/maintained by the Standards Collaborative.*

Recommendation 9: *Until a template registry is created, include all details of the template(s) used within the local CDA Implementation Guide. Do not just include the OID – include all details within the guide or as an appendix.*

Recommendation 10: *Use a single pan-Canadian CDA header, and when possible pan-Canadian CDA templates as they become available.*

Recommendation 11: *Use OID* ***2.16.840.1.113883.2.20.4*** *as a root to register Canadian CDA Templates.*

Recommendation 12: *Canada should follow a similar approach to the US and maintain all pan-Canadian templates within a single guide and/or location. [HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm)].*

Recommendation 13: *HL7 CDA documents should be exchanged and managed within an enterprise environment like those described within the Infoway EHR Blueprint or IHE ITI Technical Framework using XDS.*

Recommendation 14: *Current guidance contained within the Pan-Canadian HL7 v3 Standards (PCS) eventually be replaced/ deprecated. Canadian CDA implementations should use the information described in the pan-Canadian CDA Header Implementation Guide.*

Recommendation 15: *Canada should continue to monitor tooling solutions that can support Canada's requirements for the governance, creation and management of CDA templates. As these solutions mature Canada should identify pan-Canadian tooling requirements and solutions.*

CDA Standard and its Relationship to Implementation Guides

Unlike HL7 V3 messages that have a Universal Realm version as the starting point for many of the commonly used messages, there is no universal realm reusable instance of the CDA Standard.

The normative edition of the CDA R2 must be constrained and the specification defined within an implementation guide addressing one or more business use cases within a localised realm.

Limited "universal realm" templates and specifications exist for reuse. However, there are a number of localized (country specific) implementation guides that can be refactored with some potential for reuse within similar Canadian use cases.

In order for Canadian implementations to have a consistent approach when using the CDA Standard, this document recommends all Canadian CDA (Release 2) implementations start with the following recommendation:

Recommendation 1: Apply constraints to the CDA R2 normative specification within the Canadian Realm (pan-Canadian CDA Header, and Canadian document templates).

There are a number of CDA implementation guides that support business use cases which are the same or similar to those in Canada. These include:

- HL7 Implementation Guides for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1 – US Realm - http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG_IHE_CONSOL_DSTU_R1dot1_2012JUL.zip (HL7 Members only)
- IHE Patient Care Coordination (Medical Summaries, Referral, etc.) - http://www.ihe.net/Technical_Framework/index.cfm#pcc
- France's CDA guide for scanned documents - http://www.interopsante.org/412_p_19208/documents-publics.html
- epSOS CDA guide (Medical Summary, Lab Report) - http://www.epsos.eu/uploads/tx_epsosfileshare/D3.5.2_Appendix_C_Pivot_Document_Specifications_01.pdf
- Australia CDA guide (nehta eDischarge Summary) - http://www.nehta.gov.au/component/docman/doc_download/888-edischarge-summary-core-cda-implementation-guide-release-1-v11-draft-20091125

The above listed implementation guides demonstrate the use of a CDA header (some cases localized to a country), the use and reuse of templates, and references to multiple terminology domains. These examples lead to the second recommendation:

Recommendation 2: When possible reuse/refactor templates (document, section, entry level) from other implementation guides.

The CDA Standard and HL7 messages[1]

Both HL7 CDA and HL7 messages can be used to convey similar data. For this reason the question of when it's appropriate to use one standard over the other is frequently discussed. The question should not be whether to use one or the other as it's really a discussion of how the two approaches complement each other when solving healthcare data exchange requirements. Each approach was designed with specific solutions and requirements in mind. However since the normative CDA R2 standard was published in 2005, its use has been extended to other areas for which a message

[1] Excerpts from Ringholm Whitepaper – HL7 version 3: Message or CDA Document? – are included in this section http://www.ringholm.de/docs/04200_en.htm)

based approach would work best (based on guidance from the original standard). For Canadian implementations we have an extensive set of pan-Canadian HL7 V3 messages that can be used.

Recommendation #3: When using CDA to represent data already defined with the Pan-Canadian HL7 V3 Messages, use CDA section entries to convey this data.

CDA should be used:

- To represent **a complete snapshot in time** (it was considered complete at the time it was created)
- To **replace a paper form** but with the ability to have optional structured/coded content
- To **include the human readable portion which must be present** and is what makes it similar to a legal paper document
- Not as a mechanism for conveying transactional data between systems

For a better understanding, please refer to the original normative CDA R2 Standard. Additionally, this document includes excerpts from a Ringholm whitepaper that may help further clarify the differences.

When to Use HL7 Messages (instead of CDA)

Messages are generally used to support an ongoing process in real-time. They convey status information and updates related to one and the same dynamic business object. Messages are about "control" - they can represent requests that can be accepted or refused by the system, and there are clear sets of expectations about what the receiver must do.

- In such situations the latest version of the data is of importance to support an ongoing process. Historic versions of one and the same object are generally not of importance apart from regulatory purposes (e.g. auditing).
- Messages by and large contain "current" data.
- The more interactive and tightly coupled your communication process is, the more the use of messages is applicable.

The Pan-Canadian HL7 V3 Messages (PCS) are meant to support discrete "active data". For example let's say you want the current lab results, allergy lists, etc. The idea behind PCS messages is to provide the mechanism to maintain discrete "active data" between a Point of Service (POS) system and an EHR repository. On the other hand, if the lab results or allergy lists are exchanged via a CDA (document) they represent a snapshot in time. Even if they are represented as discrete data within the document (structured/coded – entry level data), they need to be managed at a document level and not as discrete "active data".

When to Use CDA (instead of Messages)

Documents are persistent in nature, have "static" content and tend to be used "post occurrence", e.g. once the actual process is complete. Documents are persistent "snapshots" as understood at a particular time.

- Documents contain data "as it was" when the document was originally created. For documents such as referral summaries and discharge summaries, it may be more appropriate to see the data as it was understood at the time the referral or summary was constructed

rather than viewing the data as it exists now. For example, if I want to know what a patient's active allergies are today, a CDA document might not be the best choice. However, if I only care about the list of allergies at the time of a referral or diagnosis then a CDA document would be fine.

- Documents are "passive". They capture information and allow that information to be shared, but do not drive any activity in and of themselves. Documents can be superseded and corrected, but they are still "static documents" rather than dynamic objects. For example a lab result in a document might be structured and coded (entry level data), but that lab result can't be easily managed outside the document. Whereas a structured coded lab result within a message could have the required context and event data to be managed as a discrete data.

In terms of definitive definition between when to use messages or CDA, there is no absolute clear line. This document echoes the considerations from the Ringholm Whitepaper on this subject (http://www.ringholm.de/docs/04200_en.htm) –

> *"Be aware that there is no clean white line that neatly divides the world between documents and messages. It all depends on what one is trying to achieve. Any time you're trying to drive workflow you either want messages or you'll need documents transmitted via messages with an additional non-standardized workflow layer built on top. Note the importance of conveying the document metadata next to the persistent document itself. The metadata (e.g. document status, links between the document and other documents, digital signatures) changes and is managed by the exchange of messages; the document itself doesn't change. If one chooses to support a use-case with documents, one has to deal with document metadata, be it (for example) in the form of [IHE XDS] or ebXML metadata or the metadata in HL7 v2/v3 medical records messages."*

The recommendation for messages versus CDA is to consider one of the key aspects of CDA. A CDA document is a "snapshot" as authored at one specific point in time. If you have a requirement to import data from the CDA document (for example a lab result) it can't be managed individually. You would need to maintain a link between the imported data and the document so if the document is replaced or updated the discrete data that was imported from the document will be updated as well. The document is the sole object that is managed. In a message (for example, a lab result) the status of each and every act within that message can be managed individually. It's easier to manage discrete (machine processable) data within messages than the same (or similar) machine processable data imported from a CDA.

Recommendation 4: One size does not fit all. Evaluate the best exchange paradigm (messaging or document) for each information sharing requirement.

General Guidance on Use of CDA

To determine which is the best method to represent clinical content when exchanging data, your project will need to review your requirements against documents and messages. If this process leads your project to determine that CDA is the best method, then there are a number of considerations and variables to which a "true" CDA R2 compliant implementation must adhere:

- A CDA document is wrapped by the <ClinicalDocument> element and uses and/or constrains the pan-Canadian CDA Header and a body [future CDA body (document, section, entry) templates].
- Conformant instances must validate to the HL7 CDA Schema, and to the named template(s).
- Individual implementations are always associated with an implementation guide, i.e. a document that describes how the CDA Standard must be implemented for a specific context.
- For maximum use and reuse the data types must match those used in CDA R2.
- Extensions are discouraged, but when required must be included within a CDA implementation guide and a revised CDA schema file must be produced for validation purposes. (see section on extensions for more details)
- 'Green CDA' is a technique for simplifying the creation of CDA documents for implementations. Similar to the Canadian messaging tooling, it's a 'behind the front door' technology - it is not used to create simpler or lighter XML for exchange with others - it does not go 'on the wire'. CDA 'on the wire' is the fully rendered document.
- To minimize the risk of viewing superseded information, there is a critical interdependence between clinical documents and document management systems. If CDA documents are viewed outside the context of a document management system, it cannot be known with certainty whether or not the viewed document has been revised. HL7 messages that carry CDA documents (such as the MDM messages in HL7 V2.x and the HL7 V3 Medical Records messages) convey critical contextual information that ensures accurate viewing of clinical data.

There are also some common misuses of the CDA Standard that deserve mentioning:

- The document contains entries without any textual representation. The Standard states that all attested information must be present in human readable form.
- The stylesheet as used in the project adds information not present in document (e.g. the contact details of the author). This information could have been sent as part of a CDA document. If a different stylesheet is used, this information would be lost. The standard specifies that the attested contents of the CDA document have to be faithfully rendered without adding anything which may lead the human reader to misinterpret its contents.
- The stylesheet is not based on the text as present in the CDA document, but on its entries, i.e. the details expressed in the structure. Entries may not contain the exact same information as is present in the text. A receiving system must not try and construct the human readable text from entry details.
- Using the same XML namespace for "extensions".

This is a snapshot of some general guidelines associated with HL7 CDA.

Recommendation #5: To achieve consistency in CDA implementations across Canada it's recommended to follow the CDA R2 standard per the HL7 specification (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7) and the *pan-Canadian CDA Header Implementation Guide*. New CDA implementation guides and templates should be promoted at the pan-Canadian level via the *Infoway* Standards Collaborative.

CDA Extensions

An extension is a collection of element or attribute declarations and rules for their application within the CDA Standard.

1. Extensions must be defined in a namespace other than urn:hl7-org:v3. The namespace urn:hl7-org:sdtc is reserved by the Structured Documents workgroup of HL7 for the creation and maintenance of extensions by that workgroup.
2. Extensions can add information but are not permitted to change the semantics of an existing element.
3. Extensions should be optional.
4. Extensions must be based on existing class attributes found in the HL7 Reference Information Model unless extending the datatype model, in which case they must be found in the Abstract R2 model
5. Where possible, extensions should use the same HL7 vocabularies and data types that are used by the CDA Standard.
6. Extension elements should appear at the end of a class to support schema validation

Recommendation #6: Extensions to the CDA R2 schema required for a particular implementation should be optional and brought forth to the *Infoway* Standards Collaborative to be promoted nationally and/or vetted with the HL7/IHE community. Local extensions should be considered exactly that – local only – resulting in higher costs and localized interoperability. Requirements that have pan-Canadian interest should be formalized in a subsequent version of the standard in order to maximize adoption and use of shared semantics.

An example of a CDA Extension: Frequently the drug strength is assumed to be included in the drug code itself. For example, there would be a single DIN for Tylenol 250mg tablet. However, if you want to support the communication of the drug strength attribute as a separate element to accommodate historical or patient reported data that may not be coded or may not have the strength pre-coordinated in the drug name or drug code then an extension to the CDA schema would be required. Specifically drug strength (LabeledDrug/e2e:formCode), which has been added to support communicating the strength form of the drug.

This extension to the CDA body results in changes to the CDA payload schema itself (POCD_MT00040UV), this would need to be documented using a foreign namespace as specified by the CDA Standard.

CDA Stylesheets

The CDA specification contains limited information on the use/management of a CDA stylesheet for rendering a CDA document. On a search of the word "stylesheet" in the CDA R2 standard the following is all that is returned:

"For example, the CDA requirement for human readability demands that a single stylesheet render the authenticated clinical content of any CDA document. If CDA elements were defined in the generic schema that corresponds to the sections of a document, <historyOfPresentIllness> or <Subjective>,

for example, a stylesheet would need to recognize each of these tags as section-level tags and render them accordingly."

However, for implementers of CDA the use and management of CDA stylesheets is often a significant discussion point.

The following overview of CDA stylesheet management is copied from Grahame Grieve's Health Intersections website - http://www.healthintersections.com.au/?p=90

> *"The question is how the stylesheets should be managed. Generally, there are the following 3 choices:*
>
> - *Author provides the stylesheet that is used whenever the CDA document is displayed*
> - *Community agrees to a single stylesheet that is always used*
> - *The receiving application provides its own stylesheet*
>
> *While HL7 provides cda.xsl with the CDA specification, it is not required that documents render "properly" with that stylesheet, though many implementation guides require that a document should render properly with it.*
>
> *In particular, there's still a lot that is open to stylesheets – colors, fonts, borders on tables, how to squeeze space out of the screen/page, what html structures to use, which browsers to target, and most of all, how to handle attachments. (On a related note – the HL7 cda.xsl has several issues in this space, and only primitive support for handling image attachments.)*
>
> *What else can you do with a style sheet? Well, you can first of all define your own styles for use in the styleCode attribute – your corporate look and feel, for instance. And on that subject, you can do more corporate branding like including images and stylesheets from your own web site, and make the CDA document rendering look exactly like how you want. And, in fact, you can define entities in the XML that are expanded out to commonly used sentences in the stylesheets and really save space. (Yep, people keep putting this to me as an option at CDA training courses)."*

This document does not make any recommendations on the use of stylesheets beyond pointing out that bullet two from earlier seems to be a common method for managing the stylesheet - the "community" participating in the exchange of the CDA document agree/standardize on a "reference" stylesheet. The reference stylesheet would be included with the CDA specification.

Conformance Verbs, Cardinality, Vocabulary Conformance, Canadian Data Types & Bindings

These concepts are explained within the CDA R2 Standard and ***pan-Canadian CDA Header Implementation Guide***.
Canadian data type "flavors" are recommended as long as they are not the pre-adopted Canadian data type flavors that require extensions to CDA (see the *pan-Canadian CDA Header Implementation Guide* for examples).

Data type and terminology content and binding is provided within the *pan-Canadian CDA Header Implementation Guide*.

Templates

Introduction to CDA Templates

Templates in CDA are a collection of business rules used to further constrain the CDA Standard. The purpose of doing this is most often in order to meet the requirements of a specific document exchange use case (e.g. Discharge Summary). For example, in Canada we are proposing to constrain the CDA header by applying a pan-Canadian CDA Header template. This does not "break" the standard; it adds Canadian constraints via the use of specific elements, attributes, cardinality, and terminology concept domains to make it appropriate for Canadian use. Additional templates are then used to further define and refine the pan-Canadian CDA Header and body within a narrower and more focused scope.

Templates are pre-defined structures used to:

- Express constraints such as cardinality and conformance requirements
- Define the structure of the CDA header
- Define the content of a CDA document type
- Express the structure of a textual section in a CDA document
- Express the structure of a particular element of clinical data (e.g. blood pressure, body weight, etc.)

It is then possible to assemble a CDA **implementation guide defined largely by the conformance statements contained in the listed templates.**

The top level templates in CDA are used to define specific document types. Document templates can further constrain the data contained within the CDA header and the CDA body making it appropriate for a specific use case (e.g. Discharge Summary).

Section and entry level templates are defined at a granular level and reused across document templates to simplify the reuse of common document sections and entries. For example, the creation of a template for a common document section like "family history" or "immunizations" could be replaced within a section or entry level template and reused in multiple document templates and/or CDA Implementation Guides.
From a validation perspective the use of templates within CDA documents present a challenge. A CDA document is not valid unless it conforms to the CDA schema. However, requirements contained within templates can't be validated using the CDA schema alone. The assembly of templates within a CDA document requires other technologies to perform a complete validation. At the time this document was created Schematron was the most widely used validation method for CDA documents. Schematron is a standard XML language widely used in the validation of rules defined in the CDA templates.

Recommendation #7: Use templates to constrain the CDA R2 Standard for specific use cases. This document recommends a future project establish a set of pan-Canadian templates based on "common" use cases.

Open versus Closed Templates

Open templates allow the use of all features of the CDA R2 base specification except those constrained by the template. Whereas a closed template specifies everything that is allowed and nothing further may be included.

Open templates allow implementers to develop additional structured content not currently constrained in the open template. Open templates are more common today if you find yourself searching through existing CDA templates. However, for consistent, interoperable CDA implementations it's important for a clear process to be in place for managing open templates. A process for template management is important for the use of templates in general, but given the flexibility of adding additional content with open templates it's of greater importance when promoting reuse open templates within Canada.

We do not have a recommendation at this time for the use of open or closed templates.

Recommendation #8: All templates (open or closed) should be included within the CDA section of InfoCentral or a registry and managed/maintained by the Standards Collaborative.

(Note: the governance for the management of the templates listed in the future registry needs to be determined. Processes for creating, naming, updating, reusing, etc. should be clearly defined at that time)

A Roadmap for Templates in Canada

Current State & Near Term

Today templates are primarily defined and used within CDA implementation guides. They are referenced via a unique OID (Object IDentifier) within the CDA. The complete template is defined in detail normally at the end of the guide or within an appendix. (See the *pan-Canadian CDA Header Implementation Guide* for more details on the current state)

There are several kinds of CDA templates:

- Header Templates: define the constraints to be applied on the CDA Header.
- Document Templates: define the type of the clinical document being generated. (E.g. Discharge Summary, Consultation Note, CCD, etc.)
- Section Templates: define the constraints that are applied on the sections of the CDA body.
- Entry Templates: define the constraints applied to the clinical statements within the document sections

Recommendation #9: Until a template registry is created, include all details of the template(s) used within a CDA implementation guide. Do not just include the OID – include all details within the guide or as an appendix.

Template tooling is in its infancy and there remains a significant amount of work to be done on the standardization of templates and support tools. As a starting point, it's important to clearly define the template within the implementation guide in which it is used since the guide is used as a method of versioning for the template. Template versions, OIDs, etc. are locked to the version of the implementation guide.

As templates are created within jurisdictional CDA implementation guides, some of these templates should be considered for pan-Canadian use. Templates being considered should be vetted through the appropriate Standards Collaborative Working Group (SCWG) (e.g. Labs SCWG 5for lab templates, etc.). Templates designated as pan-Canadian would be included within a future pan-Canadian CDA Implementation Guide. Jurisdictional implementation guides and related artifacts should be shared in the CDA section of InfoCentral. In the longer term it is recommended that these guides and templates be put through the Standards Collaborative Governance process to be made "officially" Canadian Draft For Use (CDFU) and future maintenance / releases of the guides and templates be part of the normal Standards Collaborative process.

Recommendation#10: Use a single Canadian CDA Header, and when possible, pan-Canadian CDA templates as they become available.

Future State

Templates are evolving and the vision within HL7 and for Canadian use is for templates to stand alone as independent entities. This means templates could be represented within XML structures that include template "header" and "body" metadata.

For template content creators and implementers to realize the full potential of templates they must evolve from their current state into a stand-alone structure. To be used and reused efficiently they should be supported by tools that aid in their creation, management and use.

For example, a properly formed template will eventually have its own identifying metadata. (See Appendix D for more details).

In the future state when templates are defined with additional metadata, the templates will have the ability to be created, saved, searched, referenced, versioned, and updated. As well, from a content authoring perspective, the author of the template should be verifiable (authoring source). The tools to support templates are emerging today, and over the next couple of years should become widely available. [See the Lantana tool (Trifolia), European DÉCOR tool, Model-Driven Health Tools (MDHT)].

Template OIDs as a Unique Identifier

Templates are referenced via the use of a unique identifier. These identifiers are referenced within other templates and CDA implementation guides. Currently, all CDA R2 based templates use OIDs as the unique identifier.

Assigning OIDs to CDA Templates does not appear to follow a consistent process through the different organizations.

HL7 has created type ontology for the OIDs in the HL7 registry to make it easier for the user community to search for OIDs. Type 10 OIDs (HL7 Registered Templates) is the type used to identify published templates created and registered by the Templates Workgroup, or by HL7 Workgroups that define and publish templates as part of their balloted standards. All the Template OIDs under this category are registered under the root OID: **2.16.840.1.113883.10** [2]**.**

[2] http://wiki.hl7.org/index.php?title=HL7_OID_Registry_Frequently_Asked_Questions

http://www.hl7.org/oid/index.cfm

Organizations such as HITSP created a new root OID different from the Template OID root defined by HL7 and added their templates under this new root OID dedicated to HISTP templates: **2.16.840.1.113883.3.88.11.**

Countries such as France and the UK seem to follow the same process as HISTP by assigning their own templates OIDs that are under the OID root of the country (E.g. France used the OID 2.16.840.1.113883.2.8.2 as a root to assign template OIDs).

Assigning Template OIDs in Canada

The OID **2.16.840.1.113883.2.20** is currently used as an OID root for HL7 Canada. The following branches are in use:

- 2.16.840.1.113883.2.20.1 : used to identify pan-Canadian Specification Release Number
- 2.16.840.1.113883.2.20.2 : used to identify pan-Canadian Conformance Profile
- 2.16.840.1.113883.2.20.3 : used to identify Pan-Canadian Value Sets and Reference Sets
- 2.16.840.1.113883.2.20.4 (NEW): to be used to for CDA identifiers including CDA templates
- 2.16.840.1.113883.2.20.5 : used to identify Code systems

Recommendation #11: Use OID 2.16.840.1.113883.2.20.4 as a root to register Canadian CDA Templates.

Jurisdictions requiring CDA template OIDS for specific use cases that are local to a jurisdiction should use a local OID registered under the root OID of the jurisdiction instead of the Canadian root OID.

Furthermore, it is important that the requests to register Canadian templates are well documented with the associated metadata to avoid the issuing of new OIDs for existing templates that have been developed by other organizations.

See the Appendix for further instructions and the OID registration form.

(Note: OIDs are only one aspect of template governance; there remain issues associated with template governance in Canada yet to be determined. Examples include consistent naming, creation/reuse of open and closed templates, etc. Please submit comments on this topic for further inclusion in future versions of this document.)

Template Tooling Requirements

Currently there are limited tools available for the creation, management and use of templates. A major challenge with template use and reuse is the fact that there are no central registries that exist today. It can be a real challenge to find and reuse templates given this gap. One of the goals of the US Consolidated CDA Implementation Guide is to have all the US based CDA templates defined in a single document – The Consolidated-CDA Guide. The guide includes document templates like CCD, and additional constraints from IHE and HITSP3. Until better tooling becomes available, a similar process is considered a near term work around for defining and listing all common pan-Canadian

[3] Implementation Guide for CDA Release 2.0, Consolidated CDA Templates (US Realm), December 2011.

level templates For the near term, Canada should follow a similar approach to the US and maintain all pan-Canadian templates within a single guide and/or location. [HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm)]

A starting point for Canadian templates is to define them within CDA implementation guides and post the guides to the CDA section of InfoCentral. The longer term solution will be to develop stand-alone templates based on a specification from the HL7 Templates working group. Developing stand-alone templates will allow us to publish templates directly to the CDA section of InfoCentral (instead of within a CDA implementation guide) and eventually in a template registry.

Recommendation #12: In the longer term Canada should follow a similar approach to the US and maintain all pan-Canadian templates within a single guide and/or location
[HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm)]

The HL7 Template Working Group has a number of artifacts that are recommended when using templates. (Registry requirements, template requirements, etc.) These can be downloaded from the template WG on the www.hl7.org website. Currently there are two projects underway, one in Europe (DÉCOR) and one in the US (Trifolia) that are built upon the HL7 template requirements and should make template searching and reuse easier. Both options will be considered for use in Canada.

Each template should have enough associated metadata describing its purpose and use to make it easily identifiable. See Appendix D for the template metadata table currently being recommended and the HL7 Template Paper. (There is no approved template standard yet.)

The following are important properties from the metadata:

- **Template Identifier** (templateId): This identifier is an OID that uniquely identifies the template. This identifier must be present and always has a value. HL7, IHE and HITSP all recommend use of an OID as the identifier, with no extension.
- **Template Name** (templateName): This is the name of the template as established by its originator. This is the secondary identifier for all templates and may not be unique.
- **Template Version** (version): A template can have a version number using the format specified by the originator of the template.
- **Template Author:** This is the source of the template; ideally these sources are pan-Canadian level clinical organizations like the Canadian Medical Association (CMA), Royal College of Physicians and Surgeons of Canada (RCPSC), Canadian Nursing Association (CNA), etc.

Template Reuse (Best Practices)

The topic of template reuse is still being defined within the HL7 community. For this reason this section will continue to evolve in future versions of this document. At the time of writing this version of the document the following are best practices for template reuse. A starting point for this discussion can be found at the following link:
http://wiki.hl7.org/index.php?title=Template_Versioning_Requirements ***(Note: this is not a draft or normative standard – it is only what is being proposed by the HL7 community)***

Some of the current ***proposed*** best practices available from HL7 on template reuse and versioning are:

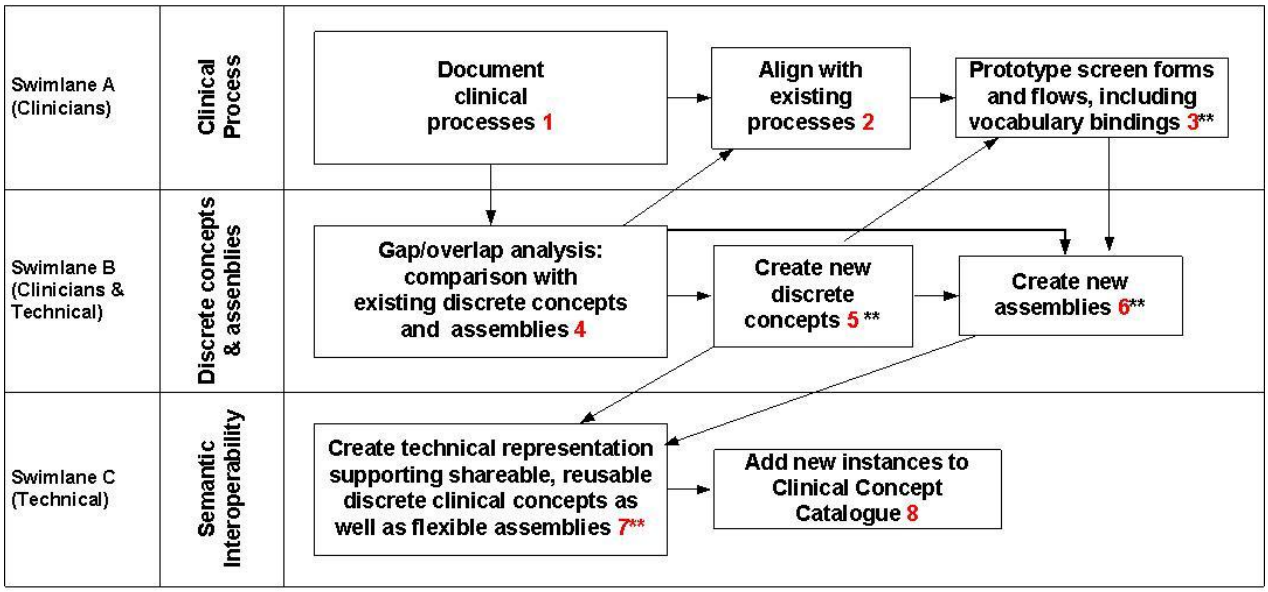
- Any edits (e.g. change in cardinality, conformance requirements, etc.) to a published template will result in a new version
- The generation of a revision has a rippling effect on dependent templates. The fundamental requirement is that one must always be able to disambiguate a template reference (both in the Implementation Guide and the Instance) to a specific version
- A template has an identifier that is the same across revisions (a.k.a. the "template ID"), and a version specific identifier (a.k.a "template version ID")
- Template ID is carried in templateId/@root. Template version ID is carried in templateId/@extension
- Template references in an Implementation Guide must include template/@root, and may include templateId/@extension. Where templateId/@extension is not present, the specific version of a template being referenced is based on a comparison of Implementation Guide publication date with template version date (and should be somehow indicated).

Templates Focusing on Clinical Content Representation

There is a process defined in an *Infoway* document titled – *"eHealth Blueprint – Supplement B – Representation of Clinical Content.doc"*. That document is available in the CDA section of InfoCentral:

https://infocentral.infoway-inforoute.ca/@api/deki/files/7036/=eHealth_Blueprint_6_-_Supplement_B_-_Representation_of_Clinical_Content_doc.pdf

The document describes a process model that can be refactored for the purpose of CDA clinical templates. The proceeding material is a refactored version of the process model for use with CDA templates:



Step 1

In this step, clinicians or providers document the clinical processes for scenarios or uses cases with which they are familiar. For example, processes such as documenting blood pressure readings,

signs of infection, pain symptoms, psychiatric history, and inspection of wounds would be documented.

Steps 2 & 3
In the next stage of the process, Clinicians work with technical resources to transform the output of Step 1 using terms that are used for that region or jurisdiction. This could include prototypes based on existing paper forms and/or screen mock-ups.

Steps 4, 5 & 6
Clinicians work with technical resources to perform the following types of analysis and maintenance activities:

- Determine if this (discrete/assembly) clinical content template exists. And if so, what is its metadata (elements & attributes, data types, vocabulary). Is the existing representation reusable? If not, create a new one.
- Conduct a gap analysis of existing similar clinical content. Compare elements & attributes for gaps and duplicates.

When creating new clinical content templates:

- Constrain an existing clinical content representation (including constraining vocabulary bindings) based on the CDA Standard.
- *(Identify jurisdictional vocabulary not part of the existing CDA vocabulary)*

Step 7 & 8
At this stage in the process, create technical representations of clinical content that can be implemented within application software:

- When possible create templates supporting semantic interoperability (entry level).
- Add new Clinical Content Templates to the CDA implementation guide. (eventually the template registry).
- (Add jurisdictional vocabulary where needed to the CDA vocabulary binding)

Exchanging CDA R2 Documents

The CDA R2 Standard provides limited guidance on the actual mechanisms and infrastructure that should be in place to exchange and manage CDA documents.

The standard states the following:

> *"The exact method by which a CDA instance is packaged and exchanged is outside the scope of this standard. While the MIME packaging method described here is not normative, it does illustrate one mechanism that meets the document exchange requirements described below."*

Exchange of documents in HL7 messages

From the perspective of a HL7 V2.x or HL7 V3 message, a CDA document can be thought of as a multimedia object that can be exchanged as a Multipurpose Internet Mail Extensions (MIME, RFC 2046) package, encoded as an encapsulated data type (ED).

The HL7 CDA R2 standards recommends the use of RFC 2557 "MIME Encapsulation of Aggregate Documents, such as HTML (MHTML)," which provides a standards-based solution to packaging the CDA document and associated files inside of a message designed to carry documents, such as the HL7 V2 or V3 Medical Records message.

In V3, CDA documents can be exchanged in any message that can exchange documents. The Act.text attribute contains the MIME package, encoded as an encapsulated data type (ED). The following is an example of how a CDA document is embedded in HL7v3 message:

```
<subject>
      <ClinicalDocument>
        <!-- Clinical Document -->
        <id extension="T0760123A" root="2.16.840.1.113883.2.4.3.23.3.20"/>
        <code code="22036-8" codeSystem="2.16.840.1.113883.6.1"
                             codeSystemName="LOINC"/>
        <!-- CDA document base 64 encoded -->
        <text mediaType="application/octet-stream" representation="B64">
           <!—Binary Image -- >
           ……
         </text>
        <!—Other elements of CDA document -- >
   …….
   </ClinicalDocument>
</subject>
```

The consequence of this approach is that many elements in the V3 message will overlap in meaning with fields in the CDA document such as: authenticator, dataEnterer, responsibleParty and custodian.

*Note: There are *no* pan-Canadian messages that exchange CDA instances. There are some pan-Canadian messages that contain document-like payloads and which are partially aligned with CDA - no more, no less. No one using those messages is CDA compliant, and in several cases, using CDA alone would not accomplish the same ends.*

Infrastructure Needed to Support CDA

The normative CDA R2 documentation contains a section titled ***The "A" in "CDA".*** This section explains the "A" is for Architecture because Release 2 of the specification has the ability to apply one or more of a hierarchical set of HL7 Templates. Architecture in the sense of the CDA specification is about the ability to support varying degrees of clinical content via the "layering on" of templates at the document, section and entry levels.

Applying template hierarchies is only one component of the architecture required for an enterprise electronic clinical document solution. If we look to enterprise content management as a model, it provides a good starting point for understanding the complexities associated with managing electronic clinical content (e.g. Documents, templates, etc.) Most architectural models for enterprise content management list the following generalized requirements, the need to:

- Create
- Manage
- Store & Retrieve
- Preserve
- Deliver

Additionally, these are normally complemented by a range of services like security & rights management, workflow, query services, document authoring, etc. There are many similarities between these models and the patterns within the *Infoway* Conceptual EHR Blueprint and the IHE IT Infrastructure Technical Framework using the XDS profile.

Recommendation #13: HL7 CDA documents should be exchanged and managed within an enterprise environment like those described within the *Infoway* EHR Blueprint or IHE ITI Technical Framework using XDS.

These environments will also need to be complemented by additional services specific to electronic clinical documentation like transformation services, authoring, security, terminology and template services. Some of these components are in their infancy and the industry in general is just beginning to support and standardize for these features. For example, template requirements, terminology services and CDA/Template registries are currently being defined within HL7 and IHE, and implementation examples, including the 3 components mentioned above, working in an orchestrated environment are difficult to find.

Today it is possible to incorporate support for CDA within base enterprise components, such as indexes, registries and repositories. Thus, at minimum, documents can be searched, retrieved and stored outside of local systems. Following *Infoway* EHR Blueprint V2 design patterns, documents should be created using patient, provider and location identifiers. The use of jurisdictional unique identifiers coupled with the use of agreed upon transport standards will facilitate the jurisdictional sharing of clinical documents.

Guidance on Past References to CDA within the Pan-Canadian HL7 V3 Standards

Pan-Canadian approach to use CDA based messages

In the pan-Canadian HL7 V3 messages, the CDA documents are exchanged as the payloads. The following pan-Canadian messages are using this model: Discharge/Care Summary, Referrals and Clinical Observation.

The pan-Canadian Clinical Documents follow the CDA structure but with the following differences:

- New components are added in the PCS messages in the Detail responses such as the following:
  - Responsible (RESP) participation.
  - PCS CDA uses a Service Delivery Location (SDLOC) and an Assigned Device (ASSIGNED) as the custodian. HL7 CDA R2 uses an organization as the custodian.
  - PCS CDA uses the general CareEvent which represents the encounter-based, condition-based and/or other care-based collections of which this record is considered to be part. CDA specifically uses the Encounters.
  - PCS CDA allows recipients to be identified but HL7 CDA does not.
  - PCS CDA allows annotations directly on the Document (and an indicator of whether annotations are present).
- In HL7 CDA R2, electronic signatures are not captured in a CDA document; both authentication and legal authentication require that a document has been signed manually or electronically by the responsible individual. In pan-Canadian CDA, there is the ability to put a signature in the Control Act wrapper which is where the author is identified. The reason being that we want to handle the authentication the same way in all PCS messages. Note that HL7 CDA R3 will allow Digital Signature in the header for author, authenticator and legalAuthenticator participations.
- PCS CDA contains links to discrete data rather than embedding discrete data within the document structure itself.

- PCS CDA has specific information structures, depending on the type of document, rather than the more general structures found in CDA.
- PCS CDA and HL7 CDA R3 use CMETs but CDA R2 does not.
- Messages exchanging CDA R2 documents in the payload use the text field to include the document itself. PCS messages are not using this field.

Another approach to convey narrative clinical information is used in other pan-Canadian messages. In this approach, narrative reports are captured in elements in the message body as an ED type. These reports are not considered a CDA document (not CDA R2 compliant).
For example, the Anatomic Pathology Result Message used for most Anatomic Pathology results enables the capture of blocks of narrative text for report content in the element 'Section Observation Value'. The data type of this field is ANY.PATH and is constrained to the following data types - ST, PQ, ED.DOCORREF or CD.LAB. Used for text or coded based observation event documentation. The following is an example of how this field is used:

```
<component1 contextControlCode="AN" typeCode="COMP"
                                                contextConductionInd="true">
  <sectionLevelObservationEvent moodCode="EVN" classCode="OBS">
    <code codeSystem="2.16.840.1.113883.6.1" code="22634-0"/>
    <statusCode code="completed"/>
    <effectiveTime xsi:type="TS" specializationType="TS.FULLDATETIME"
     value="20090319195915-0700"/>
    <value xsi:type="ST">The specimen container labeled with the patient's
                         name and as 'right new posterior margin' contains
                         unoriented pieces of fatty tissue one of these
                         measure 2.0 x 1.0 x 0.3 cm…</value>
     <performer typeCode="PRF" xsi:nil="true" nullFlavor="NI"/>
  </sectionLevelObservationEvent>
</component1>
```

Most references to CDA within the Pan-Canadian Standards are found within the HL7 V3 messages in the Implementation Guide Volume 7 – Shared Health Record. Most of the references to CDA within the V3 messages point to "Appendix A. IEHR HL7 V3 CLINICAL DOCUMENT ARCHITECTURE APPROACH" from Implementation Guide Volume 7 - Shared Health Record - R02.04.00 - 20090316.pdf

Recommendation 14: Current guidance contained within the PCS eventually be replaced/ deprecated. Canadian CDA implementations should use the standard described in the Canadian CDA Implementation Guide

CDA Risks Going Forward

There are a number of risks that exists for the successful deployment and adoption of the CDA R2 Standard. The following challenges exist:

- No pan-Canadian strategy supporting the use of CDA and templates makes it challenging to have consistent, interoperable CDA implementations.
- Lack of proper tooling and firm conformance requirements mean CDA specifications will be implemented that are not compliant with the CDA R2 specification. One of the ways to validate a CDA today is against a published XML Schema. It should be noted that the XML

Schema is not "rich enough" to validate against all the requirements as present in the original CDA class model.

- Lack of a common approach to ensure conformance to the standard
- A number of sources refer to the use of a CDA.mif, however there are few examples of its use. There is no official CDA MIF, because the CDA schemas are hand edited. There are a few sources that have created an "accurate as possible" representation of a CDA MIF, and these are semi-useful for code generation etc. However, without a MIF actually included with the base specification, it will be difficult to compare CDA in an automated environment with systems supporting its use.
- No standard approach on the use and management of CDA templates

Recommendation 15: Canada should continue to monitor tooling solutions that can support Canada's requirements for the governance, creation and management of CDA templates. As these solutions mature Canada should identify pan-Canadian tooling requirements and solutions. Without better tools and governance it will be difficult to achieve consistency and interoperability outside of local CDA deployments.

References

- IHE IT Infrastructure (ITI) Technical Framework Volume 1 - Integration Profiles August 10, 2010
- IHE Laboratory Technical Framework Volume 1 – Profiles - Revision 2.1 August 2008
- IHE Radiology Technical Framework Volume 1 – Integration Profiles - Revision 9.0 June 2008
- Archetype Definitions and Principles, openEHR Release 1.0.1, April 2007
- openEHR Archetype Profile, openEHR Release 1.0.1, April 2007
- HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), April 2007
- HL7 Clinical Document Architecture, Release 2.0
- Implementation Guide for CDA Release 2: Imaging Integration
- Implementation Guide for Common Clinical Documents
- Implementation Guide for Public Health Case Reports
- CDA White Paper v0.5.doc (Adel/George – *Infoway*)
- Naming and CDA OIDs Recommendations v02.docx (Adel – *Infoway*)
- Common issues found in implementations of the HL7 Clinical Document Architecture – Ringholm Whitepaper, 2008
- HL7 version 3: Message or CDA Document? – Ringholm Whitepaper, 2007
- eHealth Blueprint 6 – Supplement B – Representation of Clinical Content.doc (Version 1 – Discussion Paper)
- HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1 – US Realm

Appendix A – Descriptions and Definitions

Clinical Document Architecture (CDA) R2

- The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange.
- A CDA document has the following characteristics: persistence, stewardship, potential for authentication, context, wholeness, human readability
- CDA complements HL7 messaging specs
- A CDA document is a defined and complete information object that can exist outside of a messaging context
- A CDA document can be a MIME-encoded payload within an HL7 message
- The CDA has a header and a body which may be further broken into sections.
- So far, HL7 has released two versions of CDA. The CDA Release One (CDA R1) became an ANSI approved HL7 Standard in 2000, representing the first specification derived from the HL7 RIM. The CDA Release Two (CDA R2) became an ANSI-approved HL7 Standard in 2005.
- In the CDA R1, only the header part is derived from the RIM. In the CDA R2, in addition to the header part, the clinical content in the document body is also derived from the RIM. Therefore, the CDA R2 model enables the formal representation of clinical statements by using CDA entry classes.
- A CDA header defines the context of the document.
- In CDA R2, the body part can be either an unstructured blob or a structured hierarchy that involves one or more section components.
- Vocabulary domains used in CDA R2 can include HL7-defined concepts or can be drawn from HL7-recognized coding systems such as LOINC or SNOMED

Structured vs. Unstructured body

- An unstructured body contains any random content other than XML. For example a base 64 encoded document (PDF, HTML, Word, etc.). It is used to reference data that is stored externally to the CDA document or to encode the data directly inline. The following is an example of non-structured body :

```
<nonXMLBody>
        <text mediaType="application/pdf" representation="B64">
            RTDIi540KZW5kb278CjYgMCBsssvYHJK/2RTD
            ...
        </text>
</nonXMLBody>
```

The following example illustrates the use of a reference to an external document:

```
<nonXMLBody>
     <text mediaType="text/rtf" >
         <reference value='http://www.infoway-inforoute.ca/DITReport.rtf'/>
     </text>
</nonXMLBody>
```

- A structured body uses XML. The CDA specification contains a description of the allowable XML structures. It may include an arbitrary number of sections as components.

- Sections may have a title, a code (to identify its content) and text elements. The following is a sample of a structured body:

```
<structuredBody>
    <component>
        <section>
                <code code='46239-0' codeSystem='2.16.840.1.113883.6.1'
                displayName='REASON FOR VISIT+CHIEF COMPLAINT'/>
                <title>Reason for Visit/Chief Complaint</title>
                <text>Ankle Sprain</text>
        </section>
    </component>
</structuredBody>
```

- A structured body has two kinds of content: a human readable (narratives) and a software processable part (entries).

Narrative blocks vs. Entries

- The CDA narrative blocks are human readable forms. They represent content to be rendered.
- The narrative text can be structured using a predefined subset of XHTML. The following is an example of a narrative block using some XHTML tags:

```
<component>
    <section>
        <code code='10167-5' codeSystem='2.16.840.1.113883.6.1'
            displayName='PAST SURGICAL HISTORY'/>
        <title>Procedures</title>
        <text>
            <table border='1'>
                <thead>
                    <tr>
                        <th>Procedure</th><th>Date</th><th>Location</th>
                    </tr>
                </thead>
                <tbody>
                    <tr><td>Laparoscopic Cholecystectomy</td><td>9/28/2002</td>
                        <td>City Hospital</td>
                    </tr>
                    <tr><td>Cesarian Section</td><td>3/22/2002</td>
                        <td>Community Hospital</td>
                    </tr>
                </tbody>
            </table>
        </text>
    </section>
</component>
```

The following HTML table is an example on how the narrative block above will be displayed:

Procedure	Date	Location
Laparoscopic Cholecystectomy	9/28/2002	City Hospital
Cesarian Section	3/22/2002	Community Hospital

- The CDA entries represent structured content provided for further computer processing (e.g. decision support applications). CDA entries typically encode content present in the narrative block of the same section
- The CDA entries represent the structured computer-processable components within a document section.
- The sender must put all legally authenticated content in narrative blocks. A document that contains coded entries – but does not contain corresponding narrative text is not a valid CDA R2 document.
- The entries are derived from the shared HL7 Clinical Statement model. The following is an example of using a narrative block with a Substance Administration entry:

```
<component>
  <section>
     <code code="10160-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
     <title>Current Medication</title>
     <!-- Substance administration Narrative block-->
        <text>
           <list>
              <item>Ambien (Zolpidem) 10 mg daily after dinner</item>
           </list>
        </text>
    <!-- Substance administration entry -->
     <entry>
        <substanceAdministration classCode="SBADM" moodCode="EVN">
          <text>Ambien (Zolpidem) 10 mg daily after dinner</text>
          <statusCode code="active" />
          <!-- Event related administration: after dinner -->
            <effectiveTime xsi:type="EIVL_TS">
               <event code="PCV" codeSystem="2.16.840.1.113883.5.139"
               codeSystemName="TimingEvent"/>
            </effectiveTime>
            <!-- Route: oral -->
            <routeCode code="PO" codeSystem="2.16.840.1.113883.5.112"
            codeSystemName="RouteOfAdministration"/>
            <!-- Quantity per intake -->
            <doseQuantity value="10" unit="mg"/>
            <!-- Coded drug product -->
            <consumable>
               <manufacturedProduct>
                 <manufacturedLabeledDrug>
                   <code code="0024-5421-31" codeSystem="2.16.840.1.113883.12.549"
                                 codeSystemName="NDC"displayName="Ambien"/>
                 </manufacturedLabeledDrug>
               </manufacturedProduct>
            </consumable>
        </substanceAdministration>
    </entry>
```

```
  </section>
 </component>
```

HL7 CDA R3

CDA Release Three (R3) is a work in progress by the HL7 structured document work group. There is no time frame set for when this future release will pass balloting and achieve a "DSTU" or a "normative" standard designation. CDA R3 will be based on the experiences gained with the implementations of CDA R2 and will correct known deficiencies and consider proposed enhancements to the CDA R2 Standard. The main objective of the R3 release is to deliver a new updated release of the CDA Standard. It's been determined that CDA R3 will incorporate an updated Clinical Statement Model, utilize HL7 V3 data types R2 and will be updated to be consistent with the V3 Vocabulary model.

The following are some of the CDA R3 approved proposals:

- Utilize HL7 V3 data types R2
- Updated to be consistent with V3 Vocabulary model
- Use CMETs such as R_Patient, R_AssignedEntity to convey the common information
- Split Semantics and Rendering
- Extend CDA Header with new Participations and CMETs
- Allow Digital signature in the header for author, authenticator and legalAuthenticator participations
- Embed access controls specific to: individuals or roles and to entire document content, section content, template content, discrete attribute content
- Better support of Personal Healthcare Monitoring Device
- Extend CDA R2 scope to include Public Health requirements
- Support Multi-language in the CDA Body

Narrative vs. discrete information

- Discrete information represents data that can be processed by the systems. The discrete elements in a message must contain coded data to represent concepts in specific context such as dose or frequency. This is also referred as structured data. The role of structured data is allow for semantic interoperability and secondary analysis of data.
- Narrative data refers usually to unstructured human readable data. It is usually intended for rendering or simple exchange of information. The content of narrative a block is generally a text, an image or a PDF file.

Clinical Statement

- The Clinical Statement is a common pattern used for the development of all types of clinical messages.
- The Clinical Statement pattern intent is to be used within multiple HL7 Version 3 domain models to facilitate the consistent design of communications that convey clinical information.
- The Clinical Statement pattern is used to convey clinical statements through coded entries for each narrative section in CDA R2 documents
- The Clinical Statement pattern is also used in Patient Care and other related clinical domains to design HL7v3 messages.
- A Clinical Statement is an expression of a discrete item of clinical (or clinically related) information that is recorded because of its relevance to the care of a patient.
- In CDA R2 context, each clinical statement is one of the following specializations: observation, procedure, encounter, substance administration and consent.
- The following is an example of using the clinical statement pattern in CDA R2:

```
<entry typeCode="DRIV">
    <procedure classCode="PROC" moodCode="EVN">
        <id root="e401f340-7be2-11db-9fe1-0800200c9a66"/>
        <code code="52734007" codeSystem="2.16.840.1.113883.6.96" d
            displayName="Total hip replacement">
            <originalText><reference value="#Proc1"/></originalText>
            <qualifier>
                <name code="272741003" displayName="Laterality"/>
                <value code="7771000" displayName="Left"/>
            </qualifier>
        </code>
        <statusCode code="completed"/>
        <effectiveTime value="1998"/>
    </procedure>
</entry>
```

Integrating the Healthcare Enterprise (IHE) Integration profiles

- IHE is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals.
- The approach employed in the IHE initiative is to support the use of existing standards, e.g HL7, ASTM, DICOM, ISO, IETF, OASIS and others as appropriate, rather than to define new standards.
- The IHE initiative has specified several Integration Profiles to offer a common language that healthcare professionals and vendors can use to discuss integration needs of healthcare enterprises and the integration capabilities of information systems in precise terms. Integration Profiles specify implementations of standards that are designed to meet identified clinical needs.
- Integration profiles are defined in terms of IHE Actors, transactions and their content.
- The following are examples of integration profiles: Retrieve Information for Display Integration (RID), Cross-Enterprise Document Sharing (XDS), Cross Enterprise Sharing of Scanned Documents (XDS-SD), Cross-Enterprise Document Reliable Interchange (XDR)

Cross-Enterprise Document Sharing (XDS)

- The Cross Enterprise Document Sharing (XDS) integration profile focuses on providing a standards-based specification for managing the sharing of documents between any healthcare enterprise, ranging from a private physician office to a clinic to an acute care in-patient facility and personal health record systems.
- This is managed through federated document repositories and a document registry to create a longitudinal record of information about a patient within a given clinical affinity domain (e.g., a community of care). An XDS Affinity Domain is a group of healthcare enterprises that have agreed to work together using a common set of policies and share a common infrastructure.
- The current version of XDS is XDS.b in replacement of the deprecated version XDS.a. Some of the main changes introduced in the XDS.b are related to changes in the metadata format, updates in the used web services including the use of WS-Addressing, and changes in the Registry Standard.

- XDS profile proposes 4 types of actors:

- The Document Source Actor is the producer and publisher of documents. It is responsible for sending documents to a Document Repository Actor. It also supplies metadata to the Document Repository Actor for subsequent registration of the documents with the Document Registry Actor.
- The Document Consumer Actor queries a Document Registry Actor for documents meeting certain criteria, and retrieves selected documents from one or more Document Repository actors.
- The Document Registry Actor maintains metadata about each registered document in a document entry. A Registry provides an index for published documents that can be queried
- The Document Repository is responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry.

XDS document content

- The concept of a document in XDS is not limited to textual information. XDS is document content neutral, any type of clinical information without regard to content and representation is supported. This makes the XDS IHE Integration Profile equally able to handle documents containing simple text, formatted text (e.g., HL7 CDA Release 1), images (e.g., DICOM) or structured and vocabulary coded clinical information (e.g., CDA R2, CCR, CEN ENV 13606, DICOM).
- An XDS Document is the smallest unit of information that may be provided to a Document Repository
- The XDS Integration Profile manages XDS Documents as a single unit of information; it does not provide mechanisms to access portions of an XDS Document. Only the Document Sources or Document Consumers have access to the internal information of the XDS Document.
- The Document Source Actor is responsible for producing the metadata that will be submitted to the Document Registry Actor to form the XDS Document Entry that will be used for query purposes by XDS Consumer Actors.
- In order to ensure the necessary interoperability between the document sources and the document consumers, the XDS Affinity Domain must adopt policies concerning document format, structure and content. Currently, there is work underway in SCWG 10 to define a Canadian affinity domain.

The following table lists some of the document contents supported within XDS:

IHE Technical Framework Domain	Integration Profile Name	Document Content Supported
IT Infrastructure (ITI)	An example of an ITI domain content profile defining a document that may be exchanged using XDS is Cross-Enterprise Sharing of Scanned Documents (XDS-SD).	Scanned document, plain text or PDF/A, in HL7 CDA R2 format
Patient Care Coordination	An example of a PCC domain content profile defining a document that may be exchanged using XDS is Cross-Enterprise Sharing of Medical	Medical Summary in the HL7 CDA format and with CCD

	Summaries (XDS-MS). Refer to PCC TF-1 for other document content profiles.	
Radiology	Cross-Enterprise Document Sharing for Imaging (XDS-I)	Radiology Diagnostic Report in the plain text or PDF formats

Cross-Enterprise Sharing of Scanned Documents Profile (XDS-SD)

- A variety of legacy paper, film, electronic and scanner outputted formats are used to store and exchange clinical documents. These formats are not designed for healthcare documentation, and furthermore, do not have a uniform mechanism to store healthcare metadata associated with the documents, including patient identifiers, demographics, encounter, order or service information. The association of structured, healthcare metadata with this kind of document is important to maintain the integrity of the patient health record as managed by the source system.
- The XDS-SD is an XDS profile that has been developed to provide a mechanism that allows such source metadata to be stored with the document. This profile defines how to couple such information, represented within a structured HL7 CDA R2 header, with a PDF or plaintext formatted document containing clinical information.

The following is an example of CDA R2 wrapping a scanned document:

```
<ClinicalDocument xmlns="urn:hl7-org:v3"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" classCode="DOCCLIN"
moodCode="EVN" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
    <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
    <templateId root="XDS-SD OID"/>
    <!-- CDA header content here ... -->
    <component>
        <nonXMLBody>
          <!—PDF scanned content -->
            <text mediaType="application/pdf" representation="B64">
                JVBERi0xLjMKJcfsj6IKNSAwIG9iago8PC9MZW5ndGggNiAwIFIvRmlsdGV
                yIC9GbGF0ZURlY29kZT4+CnN0cmVhbQp4nGWPMWsDMQyFd/8KjfJwqmVbkr0GQqFbg
                7fQoSRNWuhBQ/4/1L67TEEYme+9J1s3CMQQRm39NLuXg8H17gK89nN1N8eLAbZ2mmH
                Xuql2QDVUhnZxa5iBcyQtoMIUM7TZHbH5KZEVDgm//SSUswbFHx/JzBLeu5yYxOIzE
                8bPcRWqdaGDmcZOBWc/9bfUNOPfOte44O9jxtcIKskqp0JZouJ5deYqeBn58ZmKtIU
                +2ptjqWQRJpGyrHDuK7CXIe2be+/1DzXQP+RlbmRzdHJlYW0KZW5kb2JqCjYgMCBvY
                moKMjAxCmVuZG9iago0SW5mbyAyIDAgUgovSUQgWzxGNENDN0FFQjU0QjM2RkIyODN
                DNUMzMjQ3OUFEMjgzRj48RjRDQzdBRUI1NEIzNkZCMjgzQzVDMzI0NzlBRDI4M0Y+X
                Qo+PgpzdGFydHhyZWYKMzAx
                MgolJUVPRgo=
            </text>
        </nonXMLBody>
    </component>
</ClinicalDocument>
```

Continuity of Care Record (CCR)

- CCR is a standard developed by ASTM (American Society for Testing and Materials).

- CCR is a core data set of administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters.
- It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care.
- The primary use case for the CCR is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient.
- The CCR may be prepared, displayed, and transmitted on paper or electronically. When prepared in a structured electronic format, strict adherence to an XML schema and an accompanying implementation guide is required to support standards-compliant interoperability.

Continuity of Care Document (CCD)

- CCD is used to exchange clinical information, including patient demographics, medications and allergies, between patients and providers
- CCD was developed as a collaborative effort between ASTM and HL7 to integrate ASTM Continuity of Care Record (CCR) and HL7 Clinical Document Architecture (CDA) CCD is the resulting specification of applying the CCR Standardized data set to constrain CDA R2 specifically for summary documents.

Green CDA

HL7 is currently exploring mechanisms to simplify its Implementation Technology Specifications (ITS). One of these initiatives is the **greenCDA** project which is working to develop a pragmatic methodology for creating simplified CDA schemas that can be transformed directly to or from normative CDA.

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

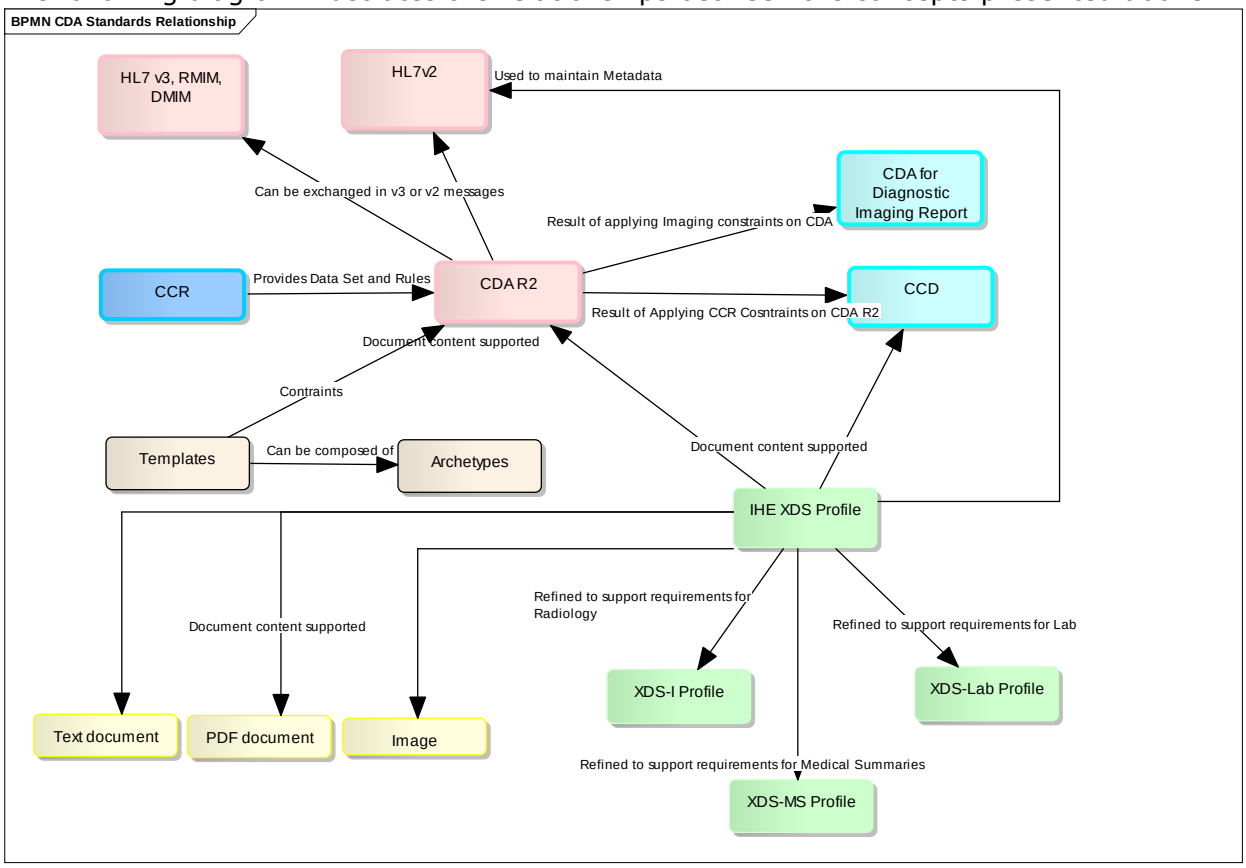
Appendix B – Relationship between CDA related standards

The following table illustrates the relationships between the different standards related to Clinical Documentation.

	Clinical Document	Template	Archetype	Clinical Statement	XDS profile
HL7v3	Document can be transmitted in HL7v3 messages using an encapsulated data (ED) type	Templates can be applied to constrain a RIM (or it may be something tighter than the RIM such as RMIM or DMIM)	Can be used to constrain HL7v3 messages	Can be used to the development HL7v3 clinical messages	The metadata in the Registry (Index) is largely based on HL7v2
CDA R2	A clinical document has the following characteristics: persistence, stewardship, potential for authentication, context, wholeness, human readability	Can be applied at the 3 levels of a CDA document to constraint the CDA specification within a particular implementation and to provide validating rule sets that check conformance to these constraints	Can be used to constrain CDA R2 level 3	Can be used to develop entries in sections of CDA R2 bodies (level 3 only)	IHE XDS is document neutral, i.e., enterprises in a clinical affinity domain decide which document format to use such as HL7 CDA. XDS has been refined to support special requirements for DICOM (XDS-I), HL7 CDA medical summaries (XDS-MS) and structured laboratory reports (XDS-Lab)
CCD		Templates are applied on CDA R2 to produce CCD documents		Represent the CCR data requirements as a set of constraints against the HL7 Clinical Statement model. Several sections in the CCD body are based on	CCD documents can be shared in the XDS

				constrained clinical statements such as Observation, Procedure, SubstanceAdministration, Encounter, Supply and Act.	
CCR				Clinical Statement are not used in CCR	CCR documents can be stored and exchanged within IHE XDS
XDS-SD document (not the Profile)		CDA R2 uses XSD-SD template to conform to the XDS-SD content profile specification			

The following diagram illustrates the relationships between the concepts presented above.



Appendix C – Pan-Canadian Request for CDA Template OID Registration

- The following are the recommended steps to register new Canadian template:
- Stakeholders complete a request and submit it to *Infoway*
- *Infoway* needs to search Canadian existing templates based on the provided metadata in the request form for similar templates.
- Stakeholder submits template to the appropriate SCWG for review and discussion
- There may be a need to consider to review the content of the submitted template (consider the constraints defined in the template and don't rely only on the metadata).
- Validate if this template is not defined by other organizations such as HL7 and IHE. Although this step is important, it is difficult to achieve as explained above.
- The submitted request may be:
    - Rejected. There is already an existing template that has the same intent and defines the same (or almost) constraints
    - Returned to the submitter with suggested changes. A good example would be when the new template can reuse existing templates instead of defining the new constraints from scratch.
    - Accepted. The metadata is then documented in a registry (The registry can be represented as an Excel file but preferably the registry information is stored in a computable format and published to the stakeholders). A new OID is then created under template OID root **2.16.840.1.113883.2.20.4** and assigned to the new template.

1.	**Summary description of the proposed template**	
Template Request Title		
Date Raised: (dd/mm/yy)		
Initiator:	**Name:**	**Jurisdiction:**
Business Rationale		
Response Required by:	☒ Date not specified, or ☐ Date _____ Rationale for date:	

1.	Detailed description of the proposed template
Details about the template:	
Constraints defined in the template:	
Associated implementation guide:	
Template Type :	☐ **Document Template** ☐ **Header template** ☐ **Section Template** ☐ **Entry Template**
Templates referenced:	
References :	

3.	Outcome:
Decision:	☐ **Approved as proposed** ☐ **Require changes** ☐ **Rejected**
Rationale:	
References:	

Appendix D – Template Metadata (from HL7 Templates WG)

This document arises from joint work of the HL7 Templates SIG and the Template Specifications project of the MnM TC.

Property Name	Type	Conf	Documentation
TemplateId	II	M	A globally unique, non-semantic, identifier for the Template. This is the primary identifier for all Templates. MIF: OID as defined by HL7. extension is the model id as defined in the HDF
templateName	String	M	A free text natural language name identifying the Template. It is anticipated that there will be far too many templates to be able to assign a unique mnemonic or meaningful name to all of them. This is the secondary identifier for all Templates MIF: business name of the model
originatingAuthorEntityID	II	M	A globally unique non-semantic identifier for the original author of the Template. MIF: header.responsibleGroup.groupId
templateIntention	Text	M	A free text natural language description of the intent and scope of the Template. The purpose is to provide the author's initial intent for the Template. In the language specified below Example: The intention may include the Realm or sub-realm within which the Template was designed to be used for. NOTE: A change to the semantic meaning or intent of a Template will constitute a new Template, not a new version of the Template. MIF: UsageNotes on the model

templateVersion	?	M	The version identifier for the Template. The ability to determine the correct version of a Template is essential to its identification. NOTE: Changes to the Template that do not change the semantics or intention of the Template will constitute a new version of the Template being created. Any change to the semantic meaning of the Template will constitute the creation of a new Template. MIF: part of the model identifier
templateDerivedModelID	II	M	The globally unique identifier of the CIM from which the Template is derived MIF: derivation reference
templateReferenceModelID	II	M	The globally unique identifier of the reference model from which the Template is derived. NOTE: For HL7 use only, we could assume that this was the RIM, and only provide a version number. But providing a full reference to the RIM enables HL7 templates to be shared with templates on other reference models in a single registry MIF: derivation reference
templateRepositoryIdentifier	URL	M	Identifier of the primary registry where the Template is located. This is a required metadata item since the core functional purpose of a Template is reuse, and things in general are much harder to reuse when they cannot be easily located. MIF: header.primaryRepository
Description			
descriptionLanguage	SET<CS>	M	The natural language in which the Template is represented MIF: description.text.language

templateDescription	Text	M	A free text natural language description of the Template. Generally, this field should be used for things such as goals, variable lists, instructions for clinical use and interpretation, literature, examples from paper world, mapping from natural language to HL7 and the model itself, etc. MIF: description annotation on the model
templateFormat	CS	M	The format of the template definition itself. HL7 Templates are always defined in MIF form, so this value is fixed to "MIF". This field is documented to allow for registry interoperability with templates in other specifications, such as CEN 13606 templates. MIF: no equivalent
evidenceSource	URL	O	A description, reference or link to the published medical knowledge that was used in the definition of this Template. MIF: requirements annotation on model
detailedDescription	Text	O	A detailed explanation of the purpose of this Template, including features of interest. This may include an indication of the intended user group for which this definition is intended. MIF: use model annotations as appropriate
cautionPoints	Text	O	A formal statement regarding when this Template should not be used, or may be used erroneously. To define roles where the Template should not be used, or should be used with care. This field is used to expand in detail on the templateIntention. MIF: usage Notes on model
Publication			

publicationStatus	CS	M	Draft Not For Use (i.e. teaching) For Production Use Withdrawn MIF: maps to approvalInfo.approvalStatus
publicationStatusChangeDate	TS	M	The date that the current value for publicationStatus was applied of the Template MIF: approvalInfo.approvalDate
publisher	?	M	The name of the author(s) institutional affiliations and contact infomation for the creators of the Template MIF: header.responsibleGroup
publishingAuthority	II?	M	The authoritative body who has reviewed the Template for clinical accuracy and relevance, and authorized it for publication MIF: header.reviewingAuthority
revisionHistory	Text	M	The free text description describing the changes in this version of the Template as compared to the previous version. Since Template versions are built off of previous versions, the net effect of this field is to function as a comprehensive historical reference of the Template MIF: everything has a revision history; this would have to built on the fly
effectiveDate	TS	O	The date after which the Template can be considered for use. Use of the Template prior to this date would be considered an invalid use of the Template MIF: approvalInfo.approvalDate
supercedingTemplate	II	O	A template that has superceded this template and should be used instead. This field can only be populated if the publicationStatus is withdrawn MIF: TBD