



**Heath Level Seven / National Library of Medicine
Electronic Health Record Project Phase II
(Contract 2004-07)**

Final Report

Marc Koehn
Patrick Loyd
Caroline Harrison

gordon point informatics

Acknowledgements

This document was developed by Gordon Point Informatics Ltd. (GPi) in fulfillment of a contract between GPi and Health Level Seven, Inc. (HL7)¹.

Funding for this project came from the US Department of Health and Human Services (HHS) through the National Library of Medicine (NLM), the Office of the Assistant Secretary for Planning and Evaluation (ASPE) as well as the Agency for Healthcare Research and Quality (AHRQ).

Contract

This project was undertaken under HL7/NLM Contract 2004-07 and EHR Meta-transaction Portion 2004-06.

Disclaimer

The content of this report does not necessarily reflect the views or policies of HL7 or HHS. The authors are solely responsible for the content.

Copyright

Copyright © 2007 Health Level Seven Inc. Public domain access may apply – please consult with HL7 Inc.

Change Log

Version	Author(s)	Change Description	Date
1.0 (1 st Draft)	M. Koehn, P. Loyd, C. Harrison	Baseline version	March 5, 2007
1.1 (Final Draft)	M. Koehn, P. Loyd, C. Harrison	Added Change Log. Incorporated changes as per B. Braithwaite, M. Shafarman, and E. Hammond feedback, Table of contents regenerated without tracking.	March 21, 2007
1.1 (Final)	M. Koehn, P. Loyd, C. Harrison	Accepted all prior changes and removed prior comments. Incorporated feedback from Suzie Beebe.	April 14, 2007
1.2 (Revised Final)	M. Koehn	Made additional minor edits and updates. Also removed “Draft” watermark.	June 26, 2007

¹ For more information about HL7 please see <https://www.hl7.org>.

Table of Contents

1.	Executive Summary	4
2.	Introduction.....	7
2.1.	Audience	7
2.2.	Background	7
2.3.	Project Structure & Team	8
2.4.	NLM EHR Phase II Project Scope	8
2.5.	Why focus on Implementation Guides?	8
2.6.	Why develop an Implementation Guide Tool?	11
2.7.	Longer-Term Implementation Guide Tool Goals.....	11
3.	“NHIN Contractor” Collaboration.....	13
3.1.	The Partners	13
3.2.	Target Transactions	13
3.3.	Project Approach.....	13
3.4.	Status	14
3.4.1.	Northrop Grumman Guide(s).....	14
3.4.2.	Status – Accenture Guide(s)	14
3.5.	Key Outcomes & Observations	15
3.5.1.	Completeness of Guides.....	15
3.5.2.	Challenges to Broad Interoperability Surfaced	15
3.5.3.	The Role of HL7 V3 came into Sharper Focus	16
3.5.4.	Go-Forward NHIN Opportunity.....	16
4.	Implementation Guide Tool	18
4.1.	Strategy & Context	18
4.2.	Functional Summary	18
4.3.	Implementation Guide Output Structure	19
5.	NCPDP Script Mapping.....	24
6.	Recommended Next Steps	25
Appendix A.	List of Deliverables	26
Appendix B.	Medication Dosage Example.....	27
B.1	Message Model	27
B.2	Annotated View	28

1. Executive Summary

The Health Level Seven/National Library of Medicine Electronic Health Record (HL7/NLM EHR) Project reflects one of two streams of work undertaken as part of a contract between the US Department of Health and Human Services (HHS) and Health Level Seven, Inc. (HL7). The National Library of Medicine (NLM) acted as the primary contracting body, with funding support also coming from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) as well as the Agency for Healthcare Research and Quality (AHRQ).

Both work streams were intended to help provide guidance to the health informatics community on the effective exchange of health information and to achieve broad-based interoperability in the health sector. While a separate vocabulary stream was focused on ensuring that Consolidated Health Informatics (CHI) vocabularies as distributed through NLM's Universal Medical Language System (UMLS) Metathesaurus are usable with HL7, the EHR stream was focused on creating HL7 V3 based implementation guide(s) and associated tooling to enable the transmission of electronic health record (EHR) data and documents between two systems, independent of source and destination architectures. The introduction of implementation guide tooling as an aspect of this project arose from the early recognition of the significance of consistency and accuracy in guide development.

In order to validate not only the guides but the process of guide development, the project was intended to engage partners at the right stage of their own infrastructure development projects to allow the guides and their use to be actually demonstrated. Moreover, the goal was to focus on key transactions to support "breakthrough" use cases from the American Health Information Community (AHIC), such as:

Laboratory	<ul style="list-style-type: none"> • Query for Lab Results • Laboratory Results Response • Clinical Document Architecture (CDA) variant
Medication	<ul style="list-style-type: none"> • Query for Medication History • Medication History Response • Clinical Document Architecture (CDA) variant
Record Locator Service	<ul style="list-style-type: none"> • Find Candidates Query; • Find Candidates Response;

The project involved the following broad activities:

Identification of a Collaboration Partner

A key objective of this project was the collaborative development of implementation guide content based on an active development project. Consequently the project team engaged the broader health IT community to qualify potential collaboration partners and ultimately undertook collaborative work with the following partners:

- **The Markle Foundation's Connecting for Health (CFH) initiative:** CFH provided an initial group through which to dialog potential implementation guide development collaboration. Although ultimately it was not possible to develop a full relationship, this early dialog helped shape the project's go forward characteristics and highlighted some of the challenges of finding projects that are at the right stage of development. It also surfaced the need for NCPDP to HL7 V3 mapping.
- **National Council for Prescription Drug Program (NCPDP) and RxHub:** The development of an NCPDP SCRIPT to HL7 V3 mapping was an early deliverable of the project and was developed in collaboration with NCPDP and RxHub.
- **Accenture & Northrop Grumman:** The core development of implementation guides was undertaken in collaboration with two contractors developing Nationwide Health Information Network (NHIN) prototypes as part of a contract with the Office of the National Coordinator for Health IT.

Implementation Guide Tool development

An Implementation Guide Tool (IGT) was developed to leverage the current HL7 development methodology and tooling portfolio – particularly those tools that support the development of message information models². By aligning the tool with the current development infrastructure, it becomes immediately useable to specification or profile developers as well as to implementers. However, given current efforts by HL7 to substantially revamp its tooling over the coming 18 – 36 months, it is clear that the IGT will need to be updated over time and, ultimately, its capabilities will need to be integrated into the new tooling to continue to support the efficient development of precise and complete implementation guide artifacts³.

Collaborative Development of Sample Guides

Sample implementation guides were developed for certain messages drawn from the Accenture and Northrop Grumman NHIN prototypes. Unfortunately, timelines did not allow these guides to be tested as originally intended, since the guides tended to reflect an ‘as built’ view rather than an input specification. However, by reflecting real transactions that were being implemented, working with our partners allowed key issues to surface, including, for example, challenges that can be anticipated in NHIN subnet to subnet communication. These observations are highlighted in the body of this report.

In addition to the successful expansion of the HL7 tooling infrastructure, through the establishment of the IGT template, this project surfaced a variety of opportunities for the HL7 community to improve its portfolio of specification products. Although these opportunities are being actively considered and, in many cases pursued among the many HL7 committees, this report provided an opportunity to consolidate some of these points and bring them to the attention of HL7’s leadership.

This report summarizes the general observations for future deliverables, and also suggests the following key next steps:

<p>Near Term (2 – 6 Months)</p>	<ul style="list-style-type: none"> • Complete the development of a sample guide to fully demonstrate the use of the IGT, including vocabulary bindings (Note that this is already funded and underway). • Review the core content and structure requirements for implementation guides that support data interchange using HL7’s Clinical Document Architecture (CDA). Based on this review, explore the feasibility of expanding the Implementation Guide Tool (IGT) to provide support to the development of CDA Implementation Guides.
<p>Medium Term (7 – 18 months)</p>	<ul style="list-style-type: none"> • Sustain efforts towards CHI value set alignment (as presently underway in the Vocabulary stream). • Continue efforts towards the development of Value Set management tools. • Establish actual (use-case focused) guides for high demand use cases - offering, where required, both message based and CDA based guides that are interoperable. • Consider publishing an IGT revision, including: <ul style="list-style-type: none"> • Adding any enhancement requirements identified by early IGT adopters; • Making adjustments as needed to ensure that an IGT can be incorporated in the HL7 ballot.
<p>Longer Term</p>	<ul style="list-style-type: none"> • Ensure that the requirements incorporated in the Implementation Guide Tool (including model annotation features of the HL7 Visio based message

² See HL7 tooling committee pages at <http://www.hl7.org/special/Committees/> for further information.

³ “Artifacts” refer to the specific specification objects typically developed; these include individual message models as well as broader specification documents such as an Implementation Guide.

(19 – 36 months)	<p>modeling tools) are brought forward into the next generation of HL7 tools.</p> <ul style="list-style-type: none">• Expand either the current IGT or any future tools devised through ongoing HL7 tooling efforts to enable production of guides that support automated conformance testing of solutions.• Expand either the current IGT or any future tools devised through ongoing HL7 tooling efforts to support not only HL7 V3 and CDA but also HL7 V2.x specifications to ease interoperability and, ultimately, migration.
------------------	--

2. Introduction

2.1. Audience

In addition to sponsors of this work, the audience for this report also includes stakeholders interested in standardized health care data interchange. In general, such stakeholders are assumed to be familiar with Health Level Seven (HL7) standards products and the associated standards development processes. For more information on Health Level Seven, please consult <http://www.hl7.org>.

2.2. Background

In an effort to provide guidance to the health informatics community on the effective exchange of health information and to achieve broad-based interoperability in the health sector, the National Library of Medicine (NLM) engaged Health Level Seven Inc. (HL7 Inc.) in a two-pronged initiative to review and address shortcomings in the areas of vocabulary alignment and implementation guide development for message-based data interchange.

These two areas resulted in the establishment of two distinct but complementary project streams as follows:

- **Vocabulary Stream:** Ensuring that Consolidated Health Informatics (CHI)⁴ vocabularies as distributed through NLM's Universal Medical Language System (UMLS) Metathesaurus⁵ are usable with HL7; and
- **EHR Implementation Guide Stream:** Creating implementation guide(s) for the use of HL7 to transmit electronic health record (EHR) data and documents between two systems, independent of source and destination architectures.

This report summarizes the outcomes of the EHR Implementation Guide stream, also known as the HL7/NLM EHR Project and, more specifically, focuses on Phase II of that stream.

Phase I was primarily focused on development of a proof-of-concept prototype for message exchange; this involved development of a Phase I prototype for exchange of Clinical Document Architecture (CDA) documents and development of a draft Table of Contents for Implementation Guides.

Phase II of the project was intended to expand both message scope (beyond CDA documents) and functional scope (reviewing new technologies through the development of a Phase II prototype or through a demonstration system).

The objectives for Phase II were subsequently refined to focus on the collaborative development and pilot testing of an HL7 Implementation Guide for the transmission of patient information between disparate electronic health record (EHR) systems while ensuring semantic interoperability. Moreover, this phase also incorporated the development of a prototype Implementation Guide Tool (IGT) given the significance of consistency and accuracy in guide development.

In addition to supporting the NLM's business objective of encouraging the development of electronic health records by removing barriers to interoperability, the project was also intended to support HL7's goal of positioning HL7 V3 as a viable and demonstrable solution component to EHR development initiatives.

⁴ For more information about the Consolidated Health Informatics initiative please see <http://www.hhs.gov/healthit/chi.html>.

⁵ For more information about the UMLS please see <http://umlsinfo.nlm.nih.gov/>.

2.3. **Project Structure & Team**

A core project team provided by Gordon Point Informatics Ltd. (GPi) worked in collaboration with an HL7 co-leader board and under the guidance of the contract management team from the Department of Health and Human Services (HHS) and the HL7 Project Manager who ensured close alignment between both the EHR and Vocabulary project streams.

HHS/NLM Contract Management Team	Vivian Auld Suzie Burke-Bebee
HL7 Project Manager	Sarah Ryan
HL7 Co-Leads	Bill Braithwaite Ed Hammond Mark Shafarman
GPi Project Team	Marc Koehn (Project Manager) Patrick Loyd (HL7 Expert) Rajie Ragbeer (HL7 Tooling Expert) Lloyd McKenzie (HL7 Tooling Expert) Caroline Harrison (Project Coordinator)

2.4. **NLM EHR Phase II Project Scope**

Through progressive refinement activities, the scope for Phase II of the HL7/NLM EHR Project was confirmed as the:

- development of an Implementation Guide Tool (IGT) that will be used to create implementation guides for HL7 V3 messaging;
- use of the IGT to support the development of an Implementation Guide for a pilot project – ideally involving “breakthrough” use case transactions, from the American Health Information Community (AHIC), such as medication history query and laboratory result communication;
- identification of HL7 standards issues in the pilot for resolution through the usual HL7 processes; and
- where depth of scope has to be limited by available time and resources, efforts were to be focused on positioning for future expansion.

2.5. **Why focus on Implementation Guides?**

Most “standards” – including V3 Ballot specifications – are not really “implementable” without some trading partner negotiation. Primary reasons for this include:

HL7 V3 specification ambiguities

HL7 V3 specifications – like other major standards frameworks – are intended to support general use cases applicable across many countries and therefore, include certain ambiguities, for example:

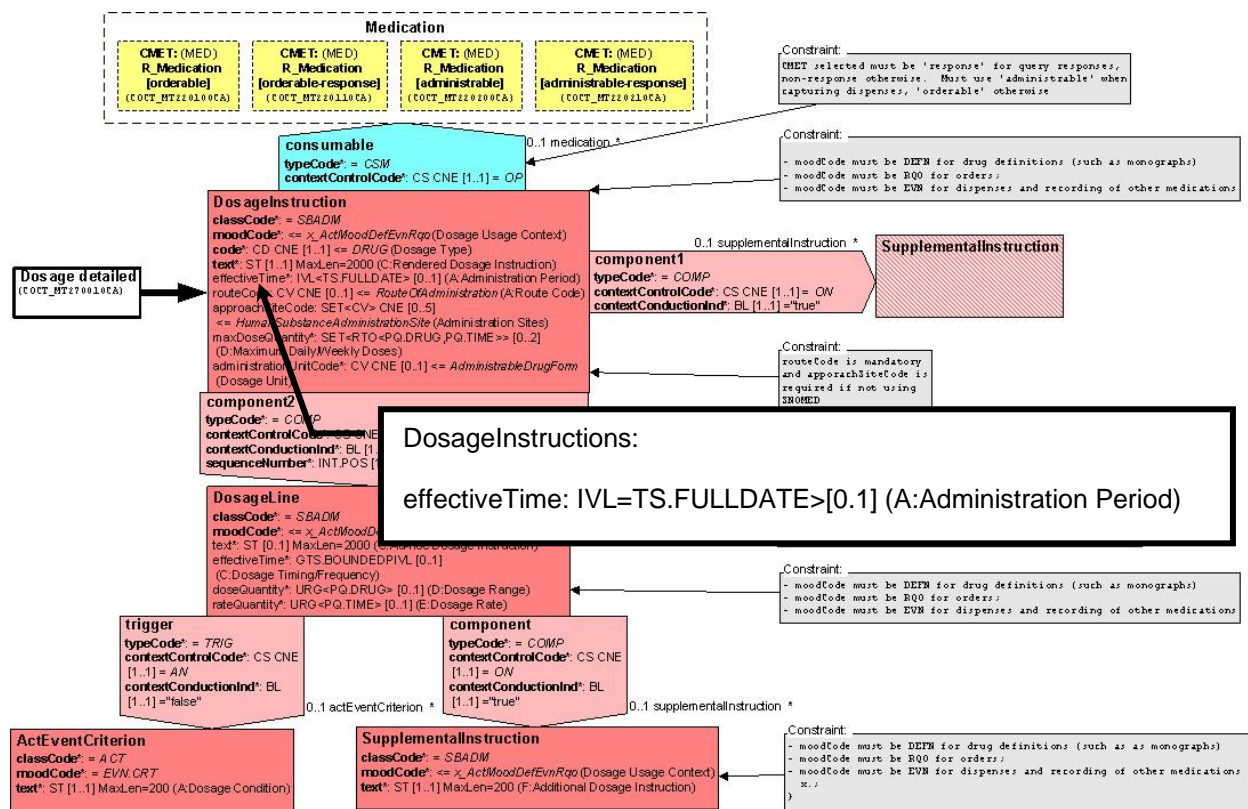
- ambiguities in core specifications such as,
 - **Optionality:** a particular attribute in a message may not be required in all exchanges. Such optionality typically must be resolved by trading partners, particularly if the attribute is critical to the use case being implemented. For example, if dose number in an immunization administration message is marked as optional then a receiver cannot anticipate receiving such data without formally confirming this with a sender.
 - **Unbounded cardinalities:** establishing a 0..* unbounded cardinality, effectively places an onus on compliant systems to accept any number of repeats for an attribute or structure. In practice this may not be realistic. For example, should a system always be able to hold an unlimited number of patient addresses?

- ambiguities in data types: data types describe how specific information such as numbers, text or geo-references are expressed in a message. Certain data types may be too complex in practice or be expressed in an unbounded manner; or
- ambiguities over coded values: contextual (e.g. context-of-use-specific) value set bindings need to be established. For example, it may be reasonable to designate a major terminology, such as LOINC® or SNOMED-CT®, for a particular coded attribute within a broad standard. However, it is unlikely that all LOINC® or SNOMED-CT® concepts are applicable for all use cases and hence the opportunity exists within an implementation guide or profile to narrow the allowable codes. Consider a laboratory result message that supports batteries or panels of observations (e.g. a Complete Blood Chemistry, or CBC, consisting of a number of observations including, for example, white blood cell count (WBC), red blood cell count (RBC), etc.). Clearly not all LOINC® codes are valid batteries or panels. Moreover, there may be a dependency between valid battery/panel codes and other observation codes that can properly be part of such a battery or panel.

HL7 V3 specifications are not necessarily easy to understand

HL7 specifications generally are not “business language” focused and therefore may be difficult to understand by business users and implementers. For example, the HL7 Reference Information Model (RIM) attribute descriptions are not really business oriented and therefore a business context is usually needed.

Consider the attribute “effectivetime” in the DosageInstructions portion of a medication dosage model:



Readers of this model have to understand the various elements using only basic titles. Moreover, very little information that explains or rationalizes the design decisions is exposed.

The following example outlines how this model could be annotated to provide better information to both business users and technical implementers:

Administration Instructions

(DosageInstruction)

Description	This comprises all specifications necessary for the dispensed product to be administered to/by the patient in a manner as intended by the prescriber.
Rationale	Allows providers to communicate intentions and to cross-check intended and actual methods of administration.
Constraints	routeCode is mandatory and approachSiteCode is required if not using SNOMED - moodCode must be DEFN for drug definitions (such as monographs) - moodCode must be RQO for orders; - moodCode must be EVN for dispenses and recording of other medications

Attributes: Administration Period

(effectiveTime)

Datatype	IVL<TS.FULLDATE>	Date-range (includes approximate start-date, end-date, center-date and duration. Only two of these properties (usually start and end) are transmitted.)
Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	1	Does not repeat
Description	The time period (begin and end dates) within which the dispensed medication is to be completely administered to/by the patient. May differ from date prescription was issued.	
Rationale	Indicates the overall time boundaries in which the person is expected to take the drug. Denotes the reference point for calculating expected exhaustion date and quantity on hand. Facilitates compliance checking. Note: TID may be interpreted differently based on situation (e.g. based on schedules of a facility).	
Implementation	Frequently only the duration (width) component is specified. E.g. 100mg tid for 10 days. In that case, the start date is presumed to be the date the prescription was written	

A tooling infrastructure that incorporates the capture of such business and implementation guidance into messaging design and then leverages the captured information into its output materials could certainly help make the resulting specifications easier to understand for implementers.

(Please see Appendix B for a full copy of this example)

Most “Standards” – including HL7 V3 – do not sufficiently express all integration requirements

For implementers to build integrated systems, additional specifications in the following areas require business decisions, for example:

- information gaps: some considerations (e.g. important business rules; transactional considerations, etc.) cannot be easily or completely specified in message models;

- implementation/roll-out conventions: formal identifier strategies (e.g. Patients, Providers, etc.) Object Identifiers (OIDs), etc.; or
- other Open Systems Interconnection (OSI) Layers: OSI Layers 1 – 6 and “7+” may also matter. These could range from basic technical connectivity considerations through to security and authentication requirements.

An “Implementation Guide” (IG) or “Integration Profile” can overcome these issues. The IG is a type of artifact that allows message and interaction specifications to be:

- constrained to fit an appropriately narrow use case;
- placed into a clear business context;
- consolidated into a set of complementary functions;
- augmented with quasi-normative (from a testable conformance perspective) and informative text at various layers of integration ranging from the basic technical exchange to business workflow integration;
- reviewed and endorsed/validated (as desired or required by a particular community of shared interest);
- comprehensively published; and
- used by software application builders, certifiers, and buyers/users to support implementation of integrated solutions.

2.6. ***Why develop an Implementation Guide Tool?***

The notion of supporting implementation guide development through applicable tooling was seen as a key way to leverage the tooling based development methodology of HL7 V3 while establishing a mechanism to drive the development of consistent implementation guide artifacts. Consequently Phase I of the project saw the conceptualization of an Implementation Guide Tool.

The Implementation Guide Tool (IGT) defines and references the Message Specification and provides implementation, compliance and conformance guidelines for use in developing software that conforms to the Message Specifications developed by an organization through the process. It will also provide additional information necessary to implement the developed Message Specifications such as business rules not specified through the message constructs.

The IGT,

- ***provides precision and efficiency:*** providing tight linkage to underlying messaging artifacts will drive precision and internal consistency of implementation guides since the current approach of re-entry risks errors and contradiction; such leveraging of the core technical artifacts also enables efficiencies in guide production;
- ***supports application of best practices:*** content templates – even if these are evolving – can allow best practices to be propagated and helps assure rigor in guide development; and
- ***facilitates guide portfolio consistency:*** format templates can help drive consistency in look and feel among guides within a broader specification portfolio – whether at the HL7 level, at a realm level or within a particular integration community.

2.7. ***Longer-Term Implementation Guide Tool Goals***

This project was intended to create a foundation based on the current HL7 tooling. However, in the longer term, implementation guides and any associated tooling will have to allow standards implementation guide and integration profile developers as well as implementers to:

- Complete the specification:
 - IGs should contain all information necessary to develop a compliant solution such that conformant messages created on disparate information systems by different programming teams using the same IG will be interoperable; and
 - tooling should be integrated with and derive as much information as possible automatically from existing or future HL7 Development tools.

- Position for programmatic conformance testing:
 - tooling should produce automated conformance tests so that any message could be analyzed for conformance with the IG.

- Establish cross-version capabilities:
 - support to document V2 and V3 messages as well as V3 CDA documents within an IG (or a set of IGs); and
 - tooling should produce an automated translator to change a V3 message or CDA Document to or from an equivalent V2 message – assuming adequate information exists in the V2(+) message.

3. “NHIN Contractor” Collaboration

3.1. *The Partners*

A key challenge for the project was to identify a collaboration partner who would be willing to work with the project team in the establishment of guides using the proposed tooling. Specifically HL7 and GPi sought practical implementations of key transactions that ideally were based on HL7 V3 with V2 mapping challenges.

Initially the project engaged the Markle Foundation’s Connecting for Health (CFH) project but the CFH project was too far along the path to consider use of the proposed V3 messaging or to retrofit their implementation guides. However, motivated by the original collaboration with CFH, work was undertaken – in collaboration with key contribution from RxHub – to map the NCPDP script medication history message to HL7 V3 (See section 5 – NCPDP Script Mapping).

With the assistance of the Government contract managers and the HL7 co-leads, the project developed briefing materials and also provided presentations at HL7 Working Group Meetings to call for other potential collaborators. Ultimately two organizations that were developing prototypes for the Nationwide Health Information Network (NHIN) agreed to participate after a request by the government EHR contract manager – the Office of the National Coordinator for Health IT (ONC). These two organizations, Accenture and Northrop Grumman not only offered solutions with HL V3 at the core but, as NHIN prototypes, these solutions reflected,

- Real world scenarios; and
- Strong transactional alignment (due to shared “breakthrough use case” driven goals).

Without the kind assistance of Accenture and Northrop Grumman it would not have been possible to have a real-world connection between guide development and an operational prototype. Given the timelines, these two initiatives resulted in guides that reflect ‘as built’ components of a solution (*i.e.* a reflection of what was constructed) rather than an input specification.

The extent to which the resulting guide outputs can be broadly shared – at least through this initiative – remains to be determined.

3.2. *Target Transactions*

The following table summarizes the target transactions that were incorporated in one or both of the guides:

Domain	Transactions
Laboratory	<ul style="list-style-type: none">• Query/Response• Unsolicited Result
Medication	<ul style="list-style-type: none">• Query/Response
Demographics	<ul style="list-style-type: none">• Admit Request

3.3. *Project Approach*

The project approach was as follows:

- HL7 tooling enhancements design and development
- Independent engagement streams with each collaboration partner ...
 - Grounding dialog with each collaboration partner;

- Basic training pertaining to extended HL7 V3 tooling to enable creation of “annotated” messaging specification (i.e. embedded documentation, tightly and rigorously coupled with specification);
- Collaboration partner team driven development of message specification content (some “as built”, some prospective);
- NLM/EHR Project team driven finalization and assembly of guides; and
- Collaboration partner review and comment.

3.4. **Status**

3.4.1. **Northrop Grumman Guide(s)**

The following summarizes the final status of the Northrop Grumman guides:

- Input materials were received for core transactions as follows:
 - Laboratory - Query Lab Result
- A prototype Implementation Guide was generated from this content.
- Northrop Grumman team actively engaged HL7 community throughout the process to address HL7 standards challenges.

Please note that the extent to which this guide can be shared with third parties remains to be determined. However, an alternate “sample” guide based on a laboratory result message is being devised through a follow-on project. Said guide can be freely shared to allow inspection of the guide tool and the current output format.

3.4.2. **Status – Accenture Guide(s)**

The following summarizes the final status of the Northrop Grumman guides:

- Input materials received for transactions as follows:
 - ADT
 - Inpatient Admission
 - Inpatient Discharge
 - Outpatient Registration
 - Inpatient Preadmission
 - Change outpatient to inpatient
 - Patient Update
 - Cancel inpatient admission
 - Cancel inpatient discharge
 - Medication
 - Intolerances
 - Laboratory
 - Specimen Received; create new specimen observation event
 - Nullify specimen observation event
 - Complete specimen observation event
 - Activate or revise active specimen observation event
 - Revise completed specimen observation event
 - Cancel specimen observation event
- A prototype Implementation Guide was generated from this content.

Please note that the extent to which this guide can be shared with third parties remains to be determined. However, an alternate “sample” guide based on a laboratory result message is being devised through a follow-on project. Said guide can be freely shared to allow inspection of the guide tool and the current output format.

3.5. Key Outcomes & Observations

3.5.1. Completeness of Guides

Collaboration with two active NHIN prototype development projects on tight timelines resulted in typical resource and schedule challenges since both projects had to develop and deliver prototypes as required by their NHIN contracts.

Although excellent collaboration occurred, the content of guides was constrained as follows:

- Solid core content for those annotated/documentated message specifications that could be made available within the collaboration timeframe was provided. However, this content reflected largely an ‘as built’ perspective rather than an input specification.
- Pilot project-specific “Vocabulary” considerations could not be addressed – but efforts are presently underway to elaborate vocabulary related issues in a more general manner through a follow-on work stream⁶.
- Limited opportunity arose to explore V3/V2 mapping capabilities (However, a separate NCPDP Script-to-V3 mapping was developed and published to test the HL7 mapping tool – See section 4 – NCPDP Script Mapping).
- No “supplemental” content (e.g. other OSI layers; operational considerations; etc.) was available. However, that is not seen as critical given the focus on semantic interoperability.

Despite these challenges, it was possible to make a number of key observations as outlined in the following sections.

3.5.2. Challenges to Broad Interoperability Surfaced

It was discovered very early on that both collaboration partners have models for Laboratory Result Transactions. Although both solutions use HL7 V3, distinct approaches in architecture resulted in variations in the applicable message specifications. These key variations in both messaging structure and architecture are outlined below.

Northrop Grumman Approach	Accenture Approach
<ul style="list-style-type: none"> • Specification is taken directly from the current HL7 standard. • Narrow / focused functionality: <ul style="list-style-type: none"> • Tightened constraints • No specimen info included • Akin to a use-case specific profile that enables tight integration. • Decentralized “query” model. • Appears to focus on edge-point vocabulary translations/normalization. 	<ul style="list-style-type: none"> • Specification is based on Oracle Health Transaction Base (HTB) product and hence from an earlier version of the HL7 V3 standard. • Broad capability: <ul style="list-style-type: none"> • Many attributes, some optional • Supports various use cases without tight constraint. • Centralized “event aggregation” model. • Appears to focus on central data store based vocabulary translation/normalization.

Please note that our observations are solely focused on potential downstream NHIN “Subnet” to “Subnet” communication consequences, and in no way are intended to make a judgment on either approach. Similar analysis can and should be undertaken in other clinical domains (e.g. medication, ADT, etc.) across various implementation architectures to ensure that “Subnet” to “Subnet” interconnectivity can ultimately be achieved.

⁶ As noted previously, a separate work stream is presently underway to devise an additional sample guide which incorporates vocabulary bindings.

Based on the two architectural approaches above, it is clear that true NHIN specifications require refined use-case based alignment to:

- Define consistent end-node specifications:
 - How does data come from clinical point of service into any given NHIN “subnet”?
 - How does a clinical point of service query through the NHIN to another data store or end point?
- Define “subnet” to “subnet” based integration. Alignment will require:
 - consistency in functional coverage (e.g. from a lab perspective: inclusion of specimen; inclusion of supporting clinical data; support for various result grouping constructs, *etc.*).
 - consistency – on a use-case by use-case basis – on the associated terminology approach.

3.5.3. The Role of HL7 V3 came into Sharper Focus

Conforming to HL7 V3 messaging standard can be beneficial in a variety of ways, for example:

- provides consistent data model to enable comparison and alignment of requirements and/or solutions – in other words, even distinct solutions can be readily contrasted since they will both be drawn from the same models;
- provides formal message development mechanism supported by tooling and now improved documentation mechanisms; and
- positions for scalable vocabulary/value set designation.

However conforming to HL7 V3 messaging standard also has its complexities, for example:

- dynamic model⁷/architecture issues need to be addressed ... various architectural patterns will need to be supported (e.g. query vs. central event aggregation vs. document oriented approaches);
- “standard” vs. “profile”: HL7 committees often working at different levels – in fact, both may be needed: International baseline standards, which may include optionality and other areas of flexibility so as to provide a foundation for many use cases, and US NHIN viable “profiles” that narrow the specification for one or more specific use cases;
- tooling regarding vocabulary domain vs. value set specification remains to be improved;
- clear OID implementation strategy is required for trading networks (e.g. NHIN);
- messaging and Clinical Document Architecture (CDA) alignment needs to be resolved;
- “hidden” stability issues need to be resolved – For example, some content that has passed membership ballot uses CMETs which have not yet passed; and
- data types require constraints and associated conformance verification.

Although these complexities are actively being considered within the broader HL7 community, this project has served to bring these items to the attention of HL7 leaders.

3.5.4. Go-Forward NHIN Opportunity

Based on the collaboration with the NHIN partners within the scope of this project. There is an opportunity to continue the dialog of establishing an interoperability framework for NHIN subnets through the establishment of applicable standards that are use-case oriented but leverage some of the HL7 V3 capabilities, For example:

- Establishment of V3 based (or multi-version) Implementation Guides based on specific use case profiles, such as,
 - general ambulatory care; and
 - inpatient settings.
- Covering various architectural patterns, such as,
 - centralized event repository vs. distributed query/response model; and
 - Transactional vs. Document Based.

⁷ The “dynamic model” generally refers to the transactions that implement a particular use case. Such a model often requires baseline assumptions about the implementation architecture.

- Aligning HL7 based standards infrastructure, baseline outputs and consensus processes with other context-of-use specific consensus processes (*e.g.* HITSP) to,
 - confirm functional coverage (*i.e.* which use cases?) of specific NHIN guides;
 - confirm functional coverage of specific NHIN transactions within the various guides; and
 - confirm baseline value set assignment for all coded attributes within the documented transactions.

4. Implementation Guide Tool

4.1. Strategy & Context

The Implementation Guide Tool (IGT) established as part of this project was focused on near term applicability and therefore leveraged the current HL7 development methodology and tooling portfolio – despite the clear challenges that current tooling represents.

It is fully understood that the longer term direction for tooling has to be aligned with significant retooling initiatives presently being planned and executed by the HL7 Tooling Committee. However, current timelines for the establishment of revised tooling, particularly in the core areas of message model development and dynamic model specification, are in the order of 12 – 36 months. Therefore, near term enhancements are forced to integrate with and leverage the existing Microsoft Visio and Microsoft Access based tools.

4.2. Functional Summary

The IGT functional components can be summarized as follows:

Enhanced and Leveraged Visio Message Modeling Environment

The current Microsoft Visio framework for message model development has been expanded over the past few years through efforts by various stakeholders. This project took those enhancements forward in two ways:

- **Minor Enhancements:** The templates and associated software was tweaked to support value set designation in addition to domain designation.
- **Leveraging Emerging Features:** Important features that had recently been contributed to the tooling, such as the ability to add attribute based business annotation (*e.g.* Rationale, Implementation Notes, Mapping Notes, *etc.*) were leveraged to allow business views of models to be generated for inclusion in implementation guides. These views reflect detailed attribute descriptions that are directly harvested from the model work and hence are not prone to cut-and-paste errors.

Dynamic Model Workbook Framework

Currently the HL7 Pub-DB tool provides the primary method for documenting a dynamic message model and for generating an XML Schema based implementation technology specification (ITS). The dynamic model reflects, for example, specific interactions being devised and documents the associated message types.

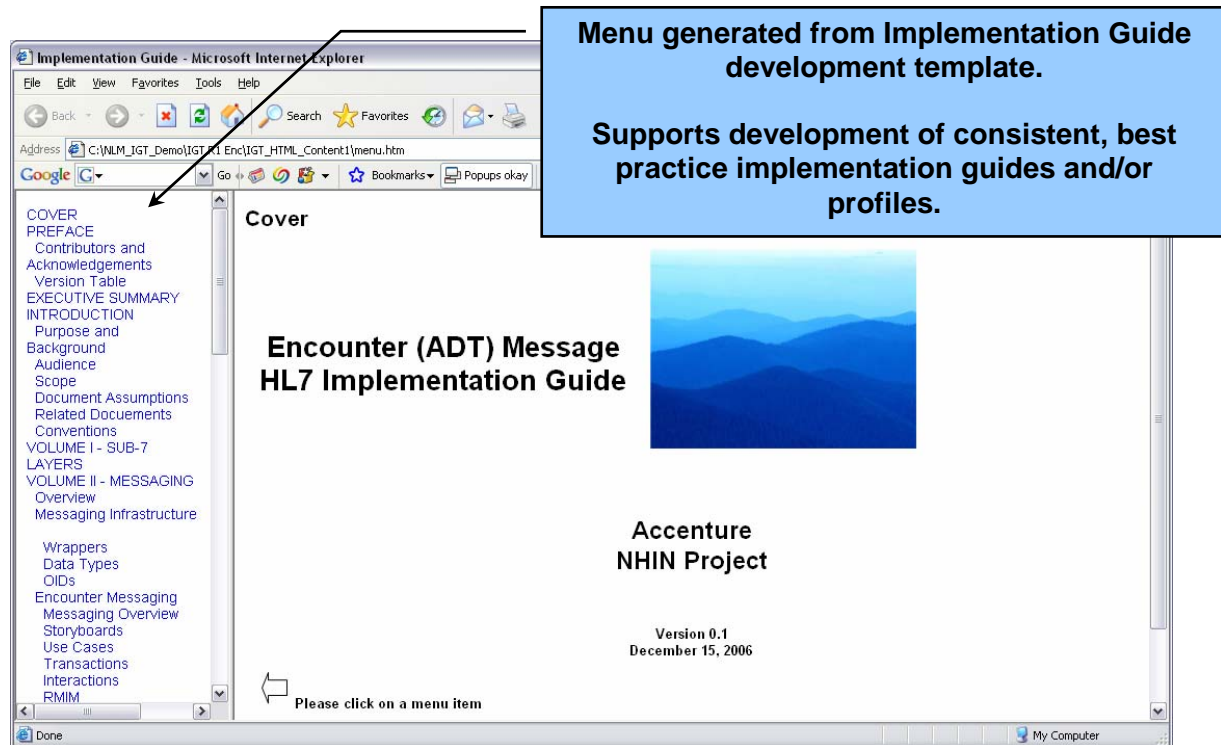
By creating a slimmed-down Microsoft Excel based version of the dynamic model that can still drive ITS outputs, the project has established a framework that can create a consistent business view of transactions (*i.e.* the set of interactions that create a business transaction) and the associated XML schema specifications.

Implementation Guide MS-Word Template

Finally a template was created that enables Implementation Guide content development based on a defined outlined that can, over time, reflect best-practices. This template enables implementation guide authors to make rigorous linkages to hard specification elements drawn from both the Visio based message models and the dynamic model workbook outlined above. The resulting guide can then be generated into an HTML based frameset.

4.3. Implementation Guide Output Structure

The implementation guide output format is similar to an HL7 ballot and provides for a menu driven framework as shown below:

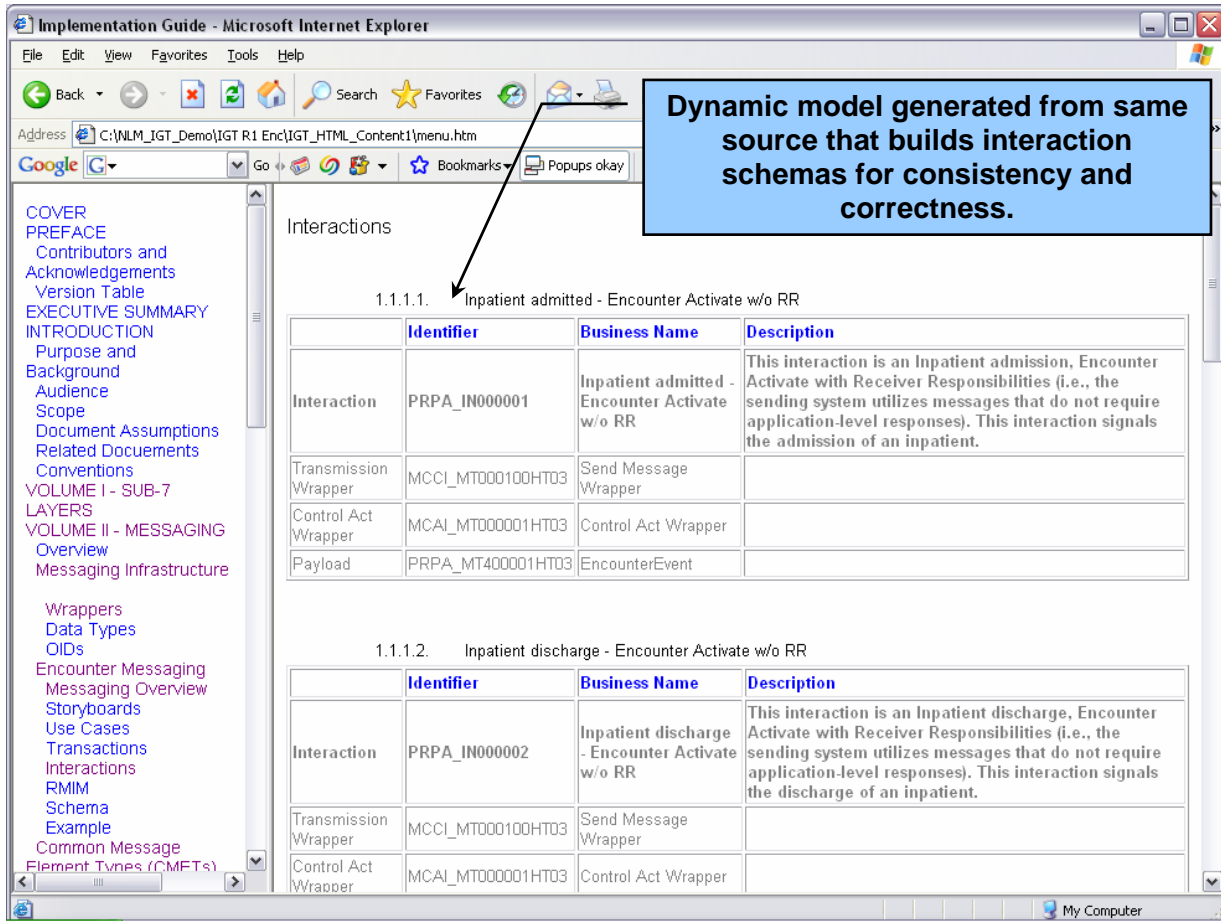


In addition to standard text, the guide has specific structures for three elements as shown below:

- Dynamic model walkthrough – Outline of the transactions and how they are assembled.
- Static Model walkthrough – Summary of the data content of a particular interaction in diagram form as well as through a list of annotated attributes.
- Preliminary Vocabulary Hooks – A preliminary mechanism for linking model attributes to the associated value sets.

[See the IGT user guide and attached example specification for details of contents.]

Dynamic Model



Implementation Guide - Microsoft Internet Explorer

Address: C:\WLM_IGT_Demo\IGT R1 Enc\IGT_HTML_Content1\menu.htm

COVER
 PREFACE
 Contributors and Acknowledgements
 Version Table
 EXECUTIVE SUMMARY
 INTRODUCTION
 Purpose and Background
 Audience
 Scope
 Document Assumptions
 Related Documents
 Conventions
 VOLUME I - SUB-7
 LAYERS
 VOLUME II - MESSAGING
 Overview
 Messaging Infrastructure

Wrappers
 Data Types
 OIDs
 Encounter Messaging
 Messaging Overview
 Storyboards
 Use Cases
 Transactions
 Interactions
 RMIM
 Schema
 Example
 Common Message
 Element Types (CMETs)

Interactions

1.1.1.1. Inpatient admitted - Encounter Activate w/o RR

	Identifier	Business Name	Description
Interaction	PRPA_IN000001	Inpatient admitted - Encounter Activate w/o RR	This interaction is an Inpatient admission, Encounter Activate with Receiver Responsibilities (i.e., the sending system utilizes messages that do not require application-level responses). This interaction signals the admission of an inpatient.
Transmission Wrapper	MCCI_MT000100HT03	Send Message Wrapper	
Control Act Wrapper	MCAI_MT000001HT03	Control Act Wrapper	
Payload	PRPA_MT400001HT03	EncounterEvent	

1.1.1.2. Inpatient discharge - Encounter Activate w/o RR

	Identifier	Business Name	Description
Interaction	PRPA_IN000002	Inpatient discharge - Encounter Activate w/o RR	This interaction is an Inpatient discharge, Encounter Activate with Receiver Responsibilities (i.e., the sending system utilizes messages that do not require application-level responses). This interaction signals the discharge of an inpatient.
Transmission Wrapper	MCCI_MT000100HT03	Send Message Wrapper	
Control Act Wrapper	MCAI_MT000001HT03	Control Act Wrapper	

Static Model (Diagram)

Implementation Guide - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address: C:\NLM_IGT_Demo\IGT R1 Enc\IGT_HTML_Content\menu.htm

Google

A_ConditionProblem [universal]

ID	Name	Description
COCT_MT930000HT01	A_ConditionProblem	[universal]
COCT_MT120500HT03		

Diagrammatic message representation directly harvested from core HL7 tooling.

Condition Problem Act Class
 subject.patient M
 Condition Problem Class Code M
 Condition Problem Code P
 Condition Problem Confidentiality Code O NaN
 Condition Problem Effective Time P
 Condition Problem ID P NaN

Static Model (Attributes)

Implementation Guide - Microsoft Internet Explorer

Address: C:\NLM_IGT_Demo\IGT R1 Enc\IGT_HTML_Content\1\menu.htm

Plans and Goals related to the problem is n registration.

1.1.1. Attributes

1.1.1.1. subject.patient
(subject.patient)

Datatype	BL	Boolean (values are 'true' or 'false')
Conformance	Mandatory	Value must always be supplied (no nulls)
Repetitions	1	Does not repeat

1.1.1.2. Condition Problem Class Code
(classCode)

Datatype	CS	Simple Code (mnemonic only)
Conformance	Mandatory	Value must always be supplied (no nulls)
Repetitions	1	Does not repeat
Code Strength	CNE	Must be coded using 'official' codeset (no un-coded text or local codes)
Code Domain	COND(under ActClass)	
Description	A code specifying the major type of Act that this Act-instance represents.	
Used by	Unspecified	

1.1.1.3. Condition Problem Code
(code)

Datatype	CD	Complex Code (includes mnemonic, code-system,
-----------------	----	---

Detailed attribute documentation harvested directly (no double entry!) from formal specification for accuracy and completeness.

(Preliminary) Vocabulary Hooks

Domain List

All vocabulary domains are listed in the v...
Refer to Appendix C in this document for...
the domains are listed in the table below:

Domain name	Business Name	Definition
AcknowledgementCondition	Message Acknowledgement Type	The codes identify the conditions under which accept acknowledgements are required to be returned in response to this message. Note that accept acknowledgement address two different issues at the same time: reliable transport as well as syntactical correct.
AcknowledgementDetailCode	Message Response Code	A site specific code indicating the specific problem being reported by this Ack Detail.
AcknowledgementDetailType	Error Message Type	A code distinguishing between errors, warnings and information messages related to the transmission of the message.
AcknowledgementType	Acknowledgment Response	This attribute contains an acknowledgement code as described in the HL7 message processing rules.
ActConsentInformationAccessReason	Consent Override Reason	Indicates why the information is being accessed
ActConsentType	Consent Type	Differentiates what form of consent is being granted
ActDetectedIssueCode	Issue Type	Identifies types of detected issues for Act class "ALRT"
ActDetectedIssueManagementCode	Issue Management Type	Codes dealing with the management of Detected Issue observations

Preliminary mechanisms to link to emerging tooling to improve vocabulary/terminology specifications within integration/ implementation profiles!!!

5. NCPDP Script Mapping

As part of this initiative, a mapping was devised between the National Council for Prescription Drug Program's (NCPDP) SCRIPT standard's Medication History Request and Response messages and equivalent HL7 V3 messages. This mapping, which also aimed to test the operation of the HL7 V2/V3 mapping tool, is available as a deliverable from this initiative.

It is important to note that the data source for the NCPDP message is from a claims repository and therefore medication history solely reflects claims history rather than medication orders or medication substance administration events. The HL7 models were constrained from the Pharmacy models available at the time, modified to add the claims information and constrained to remove all elements not present in the NCPDP message (except for those removals which would have broken conformance with the HL7 model).

The following outstanding Issues should be considered by implementers seeking closer alignment between these specifications:

- 1) There is a problem with the HL7 value set for HL7StandardVersionCode. Follow up is in progress on this item.
- 2) Need to get approval for new trigger events for this query request and response from RxSIG.
- 3) Need to add values to value sets ActSubstanceAdminSubstitutionCode, SubstanceAdminSubstitutionReason.
- 4) Need to add values to value set ObservationDiagnosisTypes.

Note that this was not meant to be a bi-directional mapping including all HL7 attributes; the mapping exercise was from NCPDP into HL7 V3.

The source of the NCPDP specifications was RxHub and the mapping effort a collaboration between Gordon Point Informatics Ltd. and RxHub. Without the assistance of the RxHub team this mapping would not have been possible.

6. Recommended Next Steps

The following next steps are proposed:

<p>Near Term (2 – 6 Months)</p>	<ul style="list-style-type: none"> • Develop a sample guide to fully demonstrate the use of the IGT, including vocabulary bindings (Note that this is already funded and underway). • Review the core content and structure requirements for implementation guides that support data interchange using HL7's Clinical Document Architecture (CDA). • Explore the feasibility of expanding the Implementation Guide Tool (IGT) to provide support to the development of CDA Implementation Guides.
<p>Medium Term (7 – 18 months)</p>	<ul style="list-style-type: none"> • Sustain efforts towards CHI value set alignment (as presently underway in the Vocabulary stream). • Continue efforts towards the development of Value Set management tools. • Establish actual (use-case focused) guides for high demand use cases - offering, where required, both message based and CDA based guides that are interoperable. • Consider publishing an IGT revision, including: <ul style="list-style-type: none"> • Adding any enhancement requirements identified by early IGT adopters; • Making adjustments as needed to ensure that an IGT can be incorporated in the HL7 ballot.
<p>Longer Term (19– 36 months)</p>	<ul style="list-style-type: none"> • Ensure that the requirements incorporated in the Implementation Guide Tool (including model annotation features of the HL7 Visio based message modeling tools) are brought forward into the next generation of HL7 tools – including those tools being presently devised through the HL7 Tooling Collaborative. • Expand either the current IGT or any future tools devised through the HL7 Tooling Collaborative to enable production of guides that support automated conformance testing of solutions. • Expand either the current IGT or any future tools devised through the HL7 Tooling Collaborative to support not only HL7 V3 and CDA but also HL7 V2.x specifications to ease interoperability and, ultimately, migration.

Appendix A. LIST OF DELIVERABLES

The deliverables from this project are posted at <http://www.hl7.org/nlmcontract/index.cfm> and include the following:

- ***HL7 NLM Phase II - Final Report - 2007-mm-dd.pdf***: This report.
- ***NCPDP2HL7MedHistoryModelsandMapping-20060427.zip***: NCPDP SCRIPT / HL7 V3 mapping.
- ***HL7-IGT-Vn.n.zip***: HL7 Implementation Guide Tool; please note that updates to this template are likely to be published through the applicable tooling committee pages at <http://www.hl7.org>.

B.2 Annotated View

[Administration Instructions](#)

[Administration Period](#) R

[Route Code](#) O

[Administration Sites](#) O 5

[Rendered Dosage Instruction](#) M

[Maximum Daily/Weekly Doses](#) R 2

[Dosage Type](#) M

[Dosage Unit](#) R

[Dosage Usage Context](#) M

[administers package component](#) R

Drug Product

Drug Code P

Drug Name M

Drug Description R

Drug Form R

dispensed in Drug Package R

Drug Container Type R

Drug Package Quantity R

drug contains Drug Ingredients R 10

Drug Ingredient Identifier R

Drug Ingredient Name R

Drug Ingredient Quantity R

Drug Does Not Contain Indicator P

or *Drug Product*

Drug Code P

Drug Name M

Drug Description R

Drug Form R

dispensed in Drug Package R

Drug Container Type R

Drug Package Quantity R

drug contains Drug Ingredients R 10

Drug Ingredient Identifier R

Drug Ingredient Name R

Drug Ingredient Quantity R

Drug Does Not Contain Indicator P

manufactured by Manufacturer R

Manufacturer Id R

Manufacturer Name M

or *Drug Product*

Drug Code P

Drug Name M

Drug Description R

Drug Form R

Drug Lot Number R

Drug Expiry Date R

drug contains Drug Ingredients R 10

Drug Ingredient Identifier R

Drug Ingredient Name R

Drug Ingredient Quantity R

Drug Does Not Contain Indicator P

drug dispensed in Drug Package R

Drug Container Type R

Drug Package Quantity R

or *Drug Product*

Drug Code P

Drug Name M

Drug Description R

Drug Form R

Drug Lot Number R

Drug Expiry Date R
drug contains Drug Ingredients R 10
Drug Ingredient Identifier R
Drug Ingredient Name R
Drug Ingredient Quantity R
Drug Does Not Contain Indicator P
drug dispensed in Drug Package R
Drug Container Type R
Drug Package Quantity R
manufactured by Manufacturer R
Manufacturer Id R
Manufacturer Name M
[augmented by Additional SIG Instruction](#) R
[Dosage Usage Context](#) M
[Additional Dosage Instruction](#) M
[consists of Structured Dosage Lines](#) R 20
[Dosage Condition](#) R
[Dosage Line Order](#) M
[Ad-hoc Dosage Instruction](#) R
[Dosage Timing/Frequency](#) R
[Dosage Range](#) R
[Dosage Usage Context](#) M
[Dosage Rate](#) R
[augmented by Additional SIG Instruction](#) R
[Dosage Usage Context](#) M
[Additional Dosage Instruction](#) M

B.2.1 Administration Instructions

(DosageInstruction)

Description	This comprises all specifications necessary for the dispensed product to be administered to/by the patient in a manner as intended by the prescriber.
Rationale	Allows providers to communicate intentions and to cross-check intended and actual methods of administration.
Constraints	routeCode is mandatory and approachSiteCode is required if not using SNOMED - moodCode must be DEFN for drug definitions (such as monographs) - moodCode must be RQO for orders; - moodCode must be EVN for dispenses and recording of other medications

B-2.1.1 Attributes

Administration Period

(effectiveTime)

Datatype	IVL<TS.FULLDATE>	Date-range (includes approximate start-date, end-date, center-date and duration. Only two of these properties (usually start and end) are transmitted.)
Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	1	Does not repeat
Description	The time period (begin and end dates) within which the dispensed medication is to be completely administered to/by the patient. May differ from date prescription was issued.	

Rationale	Indicates the overall time boundaries in which the person is expected to take the drug. Denotes the reference point for calculating expected exhaustion date and quantity on hand. Facilitates compliance checking. Note: TID may be interpreted differently based on situation (e.g. based on schedules of a facility).
Implementation	Frequently only the duration (width) component is specified. E.g. 100mg tid for 10 days. In that case, the start date is presumed to be the date the prescription was written
Used by	

Route Code

(routeCode)

Datatype	CV	Code (includes mnemonic, code-system and original text)
Conformance	Optional	Implementers may declare whether they support the concept or not
Repetitions	1	Does not repeat
Code Strength	CNE	Must be coded using 'official' codeset (no un-coded text or local codes)
Code Domain	RouteOfAdministration	The contents are constrained to the value-set bound to the domain "RouteOfAdministration" within the realm being implemented (e.g. US, Canada, etc.)
Description	This is the means by which the dispensed drug is to be administered to the patient.	
Rationale	Ensures consistency in description of routes. Provides potential for cross-checking dosage form and route. Route is an optional because it is pre-coordinated with SubstanceAdministration.code when using SNOMED.	
Used by	NCPDP	

Administration Sites

(approachSiteCode)

Datatype	SET<CV>	Set of Code (Unique collection; each occurrence includes mnemonic, code-system and original text)
Conformance	Optional	Implementers may declare whether they support the concept or not
Repetitions	5	May repeat up to 5 times
Code Strength	CNE	Must be coded using 'official' codeset (no un-coded text or local codes)
Code Domain	HumanSubstanceAdministrationSite	The contents are constrained to the value-set bound to the domain "HumanSubstanceAdministrationSite" within the realm being implemented

	(e.g. US, Canada)
Description	A value denoting the body area where the medicine should be administered. E.g. 'Right Elbow', 'Left Ear'. When multiples sites are specified they should be treated as 'AND'.
Rationale	Allows specificity when a drug can potentially be applied to different parts of the patient's body. Multiple repetitions are used when the product should be administered to multiple parts of the body. CWE is used because using a code system is not essential for understanding or analyzing the prescription. The attribute is optional because it can be pre-coordinated with SubstanceAdministration.code when using SNOMED.

Rendered Dosage Instruction

(text)

Datatype	ST	String (simple string value)
Conformance	Mandatory	Value must always be supplied (no nulls)
Repetitions	1	Does not repeat
Length	2000	Applications must support contents of at least this many characters.
Description	<p>A free form textual specification generated from the input specifications as created by the provider.</p> <p>This is made up of either an 'Ad-hoc dosage instruction' or 'Textual rendition of the structured dosage lines', plus route, dosage unit, and other pertinent administration information specified by the provider.</p>	
Rationale	<p>Allows the provider to verify the codified structured dosage information entered and ensure that the exploded instruction is consistent with the intended instructions.</p> <p>Also useful in bringing back administration instructions on query responses.</p> <p>This is mandatory as dosage instructions must always be available in rendered form.</p>	

Maximum Daily/Weekly Doses

(maxDoseQuantity)

Datatype	SET<RTO<PQ.DRUG,PQ.TIME>>	Set of Ratio of Physical Quantity and Duration (Unique collection; each occurrence ratio between includes amount and units: of mass or volume appropriate to drug quantities; and includes amount and units: seconds/minutes/hours/days/months/years)
Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	2	May repeat up to 2 times
Description	The maximum amount of the dispensed medication to be administered to the patient in a 24-hr period (doses per day) or in a 7 day period (doses per week).	

Rationale	Sets an upper boundary for the quantity of the drug to be administered over a specified period of time. Particularly useful for PRN medications.
Implementation	This field can only capture maximum doses based on explicit time periods. Dosage maximums based on other constraints such as patient lifetime, menstrual cycles must be recorded using additional dosage instruction comments.
Used by	

Dosage Type

(code)

Datatype	CD	Complex Code (includes mnemonic, code-system, translations and modifiers)
Conformance	Mandatory	Value must always be supplied (no nulls)
Repetitions	1	Does not repeat
Code Strength	CNE	Must be coded using 'official' codeset (no un-coded text or local codes)
Code System	ActCode	The content is constrained to a single code (DRUG) drawn from the code system: ActCode
Description	Distinguishes types of dosage.	
Rationale	Distinguishes between types of dosage administration and is therefore mandatory. Datatype is CD to allow for SNOMED codes.	
Implementation	For SNOMED this will pre-coordinate route, body site and potentially drug. For non-SNOMED, this will be a fixed value of DRUG.	

Dosage Unit

(administrationUnitCode)

Datatype	CV	Code (includes mnemonic, code-system and original text)
Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	1	Does not repeat
Code Strength	CNE	Must be coded using 'official' codeset (no un-coded text or local codes)
Code Domain	AdministrableDrugForm	The contents are constrained to the value-set bound to the domain "AdministrableDrugForm" within the realm being implemented (e.g. US, Canada, etc.)
Description	Identifies how the drug is measured for administration. Specified when not implicit from the drug form (e.g. puff, inhalation, drops, etc.).	
Rationale	Needed when the dosage unit is not expressed as part of the dose quantity (mg, mL) or implicit as part of the drug form (capsules, tablets). Examples are Puffs, Actuations, etc.	

Dosage Usage Context

(moodCode)

Datatype	CS	Simple Code (mnemonic only)
Conformance	Mandatory	Value must always be supplied (no nulls)
Repetitions	1	Does not repeat
Code Strength	CNE	Must be coded using 'official' codeset (no un-coded text or local codes)
Code Domain	x_ActMoodDefEvnRqo	The contents are constrained to the value-set bound to the domain "x_ActMoodDefEvnRqo" within the realm being implemented (e.g. US, Canada, etc.)
Description	<p>Indicates the context of the administration.</p> <p>moodCode = RQO, for administration instruction on orders</p> <p>moodCode = EVN, for administration instruction on dispenses</p> <p>moodCode = DEF, for administration instruction on medication definition documents/references (typically, monographs).</p>	
Rationale	Puts the class in context, and is therefore mandatory.	

B-2.1.2 Associations

administers package component

(consumable.medication1)

[Drug Product](#) (*R_MedicationOrderable.Medication*)
or [Drug Product](#) (*R_MedicationOrderable-response.Medication*)
or [Drug Product](#) (*R_MedicationAdministrable.Medication*)
or [Drug Product](#) (*R_MedicationAdministrable-response.Medication*)

Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	1	Does not repeat
Description	Identification of drug product that the instruction pertains to.	
Rationale	Allows the provider to have different instructions for different medications (in a package) within an overall therapy. For example, the dispensed drug could be Didrocal, and there will be a separate dosage instruction for each of the two drugs in the package. May also be used for Duo-Packs (e.g. vaginal products consisting of an ovule and a cream).	
Implementation	The drug only needs to be specified if the administration instruction corresponds to one part of the overall product. For example, referring to the administration of a particular product from a combo-pack	
Constraints	CMET selected must be 'response' for query responses, non-response otherwise. Must use 'administrable' when capturing dispenses, 'orderable' otherwise	

augmented by

(component1.supplementalInstruction)

[Additional SIG Instruction](#) (*SupplementalInstruction*)

Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	1	Does not repeat
Description	Indicates additional dosage instructions at the overall structured dosage level.	
Rationale	Some drugs are more effective under specific body conditions and/or time of the day. This allows providers to ensure that administration of the drug is carried out at specific time and condition that they desire.	

consists of

(component2)

[Structured Dosage Lines](#) (*Component17*)

Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	20	May repeat up to 20 times
Description	Dosage instructions may be given as textual information (as in Ad-hoc Dosage Instructions specified above) or as a structured set of dosage lines. This association allows for the specification of structured dosage lines.	
Rationale	Structured dosage lines facilitate the checking of dosage appropriateness. It also allows for the formal calculation of days supply based on administration instructions and supplied quantity.	

B.2.2 Medication

(Medication)

B.2.3 Drug Product

(R_MedicationOrderable.Medication)

Description	A pharmaceutical product intended to be supplied and/or administered to a patient. Encompasses manufactured drug products, generic classifications, prescription medications, over-the-counter medications and recreational drugs.
Rationale	Allows drugs to be clearly described and referenced. Also allows searching for and examining information about medications that can be or are being used by a patient.
Used by	NeCST

This element incorporates the model:

- [R_MedicationOrderable](#) (COCT_MT220100CA)

B.2.4 Drug Product

(R_MedicationOrderable-response.Medication)

Description	A pharmaceutical product intended to be supplied and/or administered to a patient. Encompasses manufactured drug products, generic classifications, prescription medications, over-the-counter medications and recreational drugs.
Rationale	Allows drugs to be clearly described and referenced. Also allows searching for and examining information about medications that can be or are being used by a patient.
Used by	NeCST

This element incorporates the model:

- [R_MedicationOrderable-response](#) (COCT_MT220110CA)

B.2.5 Drug Product

(R_MedicationAdministrable.Medication)

Description	A pharmaceutical product to be supplied and/or administered to a patient. Encompasses manufactured drug products, generic classifications, prescription medications, over-the-counter medications and recreational drugs.
Rationale	Allows drugs to be clearly described and referenced. Also allows searching for and examining information about medications that can be or are being used by a patient.
Used by	NeCST

This element incorporates the model:

- [R_MedicationAdministrable](#) (COCT_MT220200CA)

B.2.6 Drug Product

(R_MedicationAdministrable-response.Medication)

Description	A pharmaceutical product to be supplied and/or administered to a patient. Encompasses manufactured drug products, generic classifications, prescription medications, over-the-counter medications and recreational drugs.
Rationale	Allows drugs to be clearly described and referenced. Also allows searching for and examining information about medications that can be or are being used by a patient.
Used by	NeCST

This element incorporates the model:

- [R_MedicationAdministrable-response](#) (COCT_MT220210CA)

B.2.7 Additional SIG Instruction

(SupplementalInstruction)

Description	This is a modifier for a specific dosage line or for the entire SIG. Examples are: On empty stomach, At breakfast, before bedtime, etc.
Rationale	Adds further constraint or flexibility to the primary administration instruction.

Constraints	- moodCode must be DEFN for drug definitions (such as as monographs) - moodCode must be RQO for orders; - moodCode must be EVN for dispenses and recording of other medications { x.; }
--------------------	---

B-2.7.3 Attributes

Dosage Usage Context

(moodCode)

Datatype	CS	Simple Code (mnemonic only)
Conformance	Mandatory	Value must always be supplied (no nulls)
Repetitions	1	Does not repeat
Code Strength	CNE	Must be coded using 'official' codeset (no un-coded text or local codes)
Code Domain	x_ActMoodDefEvnRqo	The contents are constrained to the value-set bound to the domain "x_ActMoodDefEvnRqo" within the realm being implemented (e.g. US, Canada, etc.)
Description	<p>Indicates the context of the administration.</p> <p>moodCode = RQO, for administration instruction on orders</p> <p>moodCode = EVN, for administration instruction on dispenses</p> <p>moodCode = DEF, for administration instruction on medication definition documents/references (typically, monographs).</p>	
Rationale	Puts the class in context, and is therefore mandatory.	

Additional Dosage Instruction

(text)

Datatype	ST	String (simple string value)
Conformance	Mandatory	Value must always be supplied (no nulls)
Repetitions	1	Does not repeat
Length	200	Applications must support contents of at least this many characters.
Description	A free form textual description of extended instruction regarding the administration of the drug.	
Rationale	<p>Allows for expression of non-codable qualifiers such as: 'on an empty stomach', 'add water' etc; which do not affect calculations of frequencies or quantity.</p> <p>This attribute is marked as 'mandatory' as it is the only information that can be specified here.</p>	
Used by		

B.2.8 Structured Dosage Lines

(Component17)

Description	This information, along with the order/sequence of the dosage lines, constitutes the details of a structured dosage instruction.
Rationale	Enables SIG instructions to be discretely specified. Also, supports scaling doses and parallel dose specification.
Constraints	- moodCode must be DEFN for drug definitions (such as monographs) - moodCode must be RQO for orders; - moodCode must be EVN for dispenses and recording of other medications Either an Ad-hoc Dosage Line or (Dosage Timing/Frequency + Dosage Range + possibly Dosage Rate) may be specified t one time }

B-2.8.4 Attributes

Dosage Condition

(dosageLine.trigger.actEventCriterion.text)

Datatype	ST	String (simple string value)
Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	1	Does not repeat
Length	200	Applications must support contents of at least this many characters.
Description	A free-form textual description of condition that must be met before the product may be administered to/by the patient. Example: When pressure exceeds 150/90 - Take 2 tabs	
Rationale	Allows un-coded specifications of conditions in which the medication should be taken.	
Used by		

Dosage Line Order

(sequenceNumber)

Datatype	INT.POS	Positive Integer (Greater than or equal to one)
Conformance	Mandatory	Value must always be supplied (no nulls)
Repetitions	1	Does not repeat
Length	2	Applications must support contents of at least this many characters.
Description	Indicates the order in which dosage lines should be performed. Ensures that each step of multiple and complex SIGs (e.g ramp up/down) is in the desired order. Dosage lines with the same sequence number should be performed in parallel. E.g. 2 tabs tid for 3 days (sequence 1) and then 1 tab tid for 4 days (sequence 2) E.g. 1 tab in the morning (sequence 1) and 2 tabs at bedtime (sequence 1)	
Rationale	Clearly expresses the order of each dosage line to ensure the correct dosage is	

	given. Element is mandatory to ensure that dosage lines are specified and followed in the order intended.
Implementation	Need examples to illustrate use of sequence lines with 'ANDs' and 'THENS'.
Used by	

Ad-hoc Dosage Instruction

(dosageLine.text)

Datatype	ST	String (simple string value)
Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	1	Does not repeat
Length	2000	Applications must support contents of at least this many characters.
Description	A free form description of how the dispensed medication is to be administered to the patient.	
Rationale	Not all dosage instructions can easily be expressed in formal terms Allows dosage instructions to be sent across as one string of information without breaking it up.	
Implementation	This field must not be used for components of the prescription that are coded elsewhere.(e.g. Coded Dosage Timing).	
Used by	eScript	

Dosage Timing/Frequency

(dosageLine.effectiveTime)

Datatype	GTS.BOUNDEDPIVL	Outer-bounded repeating interval (allows overall start and end, as well as repeating time-based frequency including frequency ranges)
Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	1	Does not repeat
Description	A structure describing the frequency (how often the drug is to be administered), offset (elapse time between administrations) represented by one line of dosage administration instruction. Includes the overall time-period the dosage instruction applies.	
Rationale	Together with the dose quantity, indicates the overall quantity of drug.	
Used by		

Dosage Range

(dosageLine.doseQuantity)

Datatype	URG<PQ.DRUG>	Range of Physical Quantity (Range between low and high values of includes amount and units: of mass or volume appropriate to drug quantities)
Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	1	Does not repeat
Description	This specifies the minimum and maximum amount of the medication to be taken during a single administration.	
Rationale	Enables the checking of administration compliance that could results in fill-too-soon/fill-too-late contraindications. Supports circumstances where the dose can vary. (e.g. 1-2 tablets)	
Implementation	Where no range is needed, a single value should be specified as the center, with a width of 0.	
Used by		

Dosage Usage Context

(dosageLine.moodCode)

Datatype	CS	Simple Code (mnemonic only)
Conformance	Mandatory	Value must always be supplied (no nulls)
Repetitions	1	Does not repeat
Code Strength	CNE	Must be coded using 'official' codeset (no un-coded text or local codes)
Code Domain	x_ActMoodDefEvnRqo	The contents are constrained to the value-set bound to the domain "x_ActMoodDefEvnRqo" within the realm being implemented (e.g. US, Canada, etc.)
Description	Indicates the context of the administration. moodCode = RQO, for administration instruction on orders moodCode = EVN, for administration instruction on dispenses moodCode = DEF, for administration instruction on medication definition documents/references (typically, monographs).	
Rationale	Puts the class in context, and is therefore mandatory.	

Dosage Rate

(dosageLine.rateQuantity)

Datatype	URG<PQ.TIME>	Range of Duration (Range between low and high values of includes amount and units: seconds/minutes/hours/days/months/years)
Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	1	Does not repeat
Description	For intravenous and other such routes, this is the time period over which one dose is to be administered. The flow rate is determined by dividing the dose quantity by	

	the Dosage rate.
Rationale	Required for intravenous administration

B-2.8.5 Associations

augmented by

(dosageLine.component.supplementalInstruction)

[*Additional SIG Instruction \(SupplementalInstruction\)*](#)

Conformance	Required	Implementers must support, but only supply data when it is available
Repetitions	1	Does not repeat
Description	Indicates additional riders that may be put on a SIG. Each dosage line or the entire set of dosage lines may be augmented by a modifier that puts a rider on the administration. Examples of such modifiers include: At bed time, before breakfast, etc	
Rationale	Some drugs are more effective under specific body conditions and/or time of the day. This allows providers to ensure that administration of the drug is carried out at specific time and condition that they desire.	