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HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2 STU Release 1.1 – US Realm the Electronic Initial Case Report (eICR)

HL7 Standard for Trial Use

January 2017

Volume 1 – Introductory Material

Publication of this standard for trial use and comment has been approved by Health Level Seven International (HL7). This draft standard is not an accredited American National Standard. The comment period for use of this draft standard shall end 18 months from the date of publication. Suggestions for revision should be submitted at http://www.hl7.org/dstucomments/index.cfm.

Following this 18 month evaluation period, this draft standard, revised as necessary, will be submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. Implementations of this draft standard shall be viable throughout the normative ballot process and for up to six months after publication of the relevant normative standard.

Structure of This Guide

Two volumes comprise this *HL7 Implementation Guide for CDA® Release 2: HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2, Standard for Trial Use Release 1.1*. Volume 1 provides narrative introductory and background material pertinent to this implementation guide, including information on how to understand and use the templates in Volume 2. Volume 2 contains the normative HL7 Clinical Document Architecture, Release 2 (CDA R2) templates for this guide along with lists of all templates, code systems, value sets, and changes from the previous version.

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Contents

1 INTRODUCTION

1.1 Purpose

The purpose of this *HL7 Implementation Guide for CDA® Release 2: HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2, Standard for Trial Use Release 1.1* implementation guide (eICR IG) is to specify a standard for the creation of an electronic initial case report (eICR) in Clinical Document Architecture, Release 2 (CDA R2) US Realm format. The submission of public health case reports for specific infectious and non-infectious conditions is required by law in all States and Territories in the United States. In addition to supporting critical public health functions in State, Local, and Territorial Public Health Agencies (PHAs), the data from these case reports will also indirectly support notifications between PHAs and to the Centers for Disease Control and Prevention (CDC) for the Nationally Notifiable Disease Surveillance System (NNDSS) and nationwide disease monitoring.

This interoperability standard will enable the reporting of events of public health interest from clinical care Electronic Health Record (EHR) technology and associated workflows. It offers the potential of enabling improved public health case reporting by facilitating information exchange between clinical care and public health with less burden for both. Doing so may also involve other new interoperability standards and potential functional changes in EHRs and public health surveillance systems. Case reporting from EHRs is also important to public health surveillance for under-reported clinical cases, emergency management of new conditions and for conditions for which a laboratory result is not a definitive criterion. Case reporting from EHRs complements electronic laboratory reporting by providing critical clinical and demographic data that may not be included in laboratory reports.

The electronic initial case report (eICR) is termed “initial” because the report may be the first report made to public health from the clinical provider, containing just enough pertinent data for PHAs to initiate investigation or other appropriate public health activities as necessary. In some instances a case report may be initiated after a phone call is made to public health in the event that an immediately telephonically reportable event is suspected. These electronic reports could be manually initiated by the clinician, or may be automatically initiated by the EHR when updated patient data is matched against a series of public health reportable condition trigger codes. The eICR will then convey initial case data to a PHA that intends to support all reportable conditions in all jurisdictions to ease integration by EHR vendors and clinical care organizations so they can support this critical public health function. Common data elements for the eICR were identified by a task force of the Council of State and Territorial Epidemiologists (CSTE). The data for the eICR are drawn from those supported in certified EHRs and are considered critical for reporting or the initiation of a public health investigation.

In some circumstances the eICR will be all that is needed to support public health reporting. Having electronic case reports on reportable conditions sent from EHRs and received by PHAs will represent a significant accomplishment of interoperability between healthcare and public health. The eICR may lead to the reporting of additional data or follow-up by the PHA to confirm reportability, provide condition-specific or public health jurisdiction-specific case data, and/or support public health investigation, contact tracing, and/or countermeasure administration.

The eICR itself may be conveyed or referenced by a number of different transport methods. It will serve as input to reportability evaluation, including that performed by public health decision support systems, such as the CSTE/CDC Reportable Conditions Knowledge

Management System (RCKMS[1]) and others. The ONC Structured Data Capture (SDC) initiative standard may be a good complement to the eICR for the purpose of manually capturing supplemental disease-specific data that may not be available in the EHR into forms. While out of scope for this IG, receiving an eICR will also allow PHAs to communicate the reportability of a condition, along with other relevant public health information, back to clinical care personnel.

1.2 Audience

This IG is designed to provide EHR vendors with the specifications for developing the functionality of EHRs used in hospitals and by ambulatory care providers to report potential cases of reportable conditions to PHAs. This IG is designed to provide public health surveillance systems developers the specifications for implementing functionality used by PHAs to receive, process, and store or archive the eICRs. The IG will also be informative to health care providers, public health staff, analysts, and health information exchange organizations among others. Users of this IG must be familiar with the details of the HL7 CDA R2 document construction and the *Consolidated CDA Templates for Clinical Notes, DSTU 2.1* (C-CDA R2.1) templates. This guide is not intended to be a tutorial on that subject.

1.3 Organization of the Guide

This implementation guide is organized into two volumes. Volume 1 contains primarily narrative text describing this Implementation Guide, whereas Volume 2 contains normative CDA R2 template definitions.

1.3.1 Volume 1 Introductory Material

This document, Volume 1, provides an overview of Clinical Document Architecture, Release 2 (CDA R2), summaries of recent changes to the standard, and information on how to understand and use the CDA R2 templates provided in Volume 2.

Chapter 1—Introduction

Chapter 2—Use Case for eICR. This section describes the use case for the eICR along with the overall flow, assumptions, conditions, actors, roles and scenarios.

Chapter 3—CDA R2 Background. This section contains selected background material on the CDA R2 base standard, to aid the reader in conceptualizing the "templated CDA" approach to implementation guide development.

Chapter 4—Using This Implementation Guide. This section describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA R2 templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this guide.

[1] www.cste.org/group/RCKMS

Chapter 5— eICR IG Specific Conformance Guidance. This section describes conformance guidance that is specific to this eICR IG.

Chapter 6— eICR Data Requirements. This section describes CSTE identified data elements, illustrates the eICR data model and the related CDA template hierarchy. It also provides mappings between the CSTE identified data elements and both the eICR data model and the CDA template hierarchy.

Appendices— The Appendices include a list of acronyms and abbreviations, a high-level change log and a summary of extensions to CDA R2.

1.3.2 Volume 2 CDA R2 Templates and Supporting Material

Volume 2 includes CDA R2 templates and prescribes their use for a set of specific document types. The main chapters are:

Chapter 1—Document-Level Templates. This chapter defines the eICR document-type and its specific header constraints and references the required and optional section-level template containments.

Chapter 2—Section-Level Templates. This chapter defines the section-level templates referenced within the document and references the required and optional entry-level template containments.

Chapter 3—Entry-Level Templates. This chapter defines entry-level templates, called clinical statements. Machine processable data are sent in the entry templates. The entry templates are referenced by one or more section templates. Entry-level templates are always contained in section-level templates, and section-level templates are always contained in a document.

Chapter 4—Participation and Other Templates. This chapter defines templates for CDA R2 participants (e.g., author, performer) and other fielded items (e.g., address, name) that cannot stand on their own without being nested in another template.

Chapter 5—Template Ids in This Guide

Chapter 6—Value Sets in This Guide

Chapter 7—Code Systems in This Guide

Chapter 8—Changes from Previous Version. Details changes to updated templates in this IG. (Does not list templates that are new to this version of the IG - these are listed here: Volume 2 Summary of Changes.

1.4 Background

State, Local and Territorial laws and regulations require the reporting of cases and, at times, suspected cases of certain infectious and non-infectious conditions to public health agencies to support disease monitoring and surveillance. For the purpose of this implementation guide, related notifications from PHAs to the Centers for Disease Control and Prevention (CDC) and between PHAs are not in scope. Transmission of reportable laboratory results is helpful in identifying cases. Clinical laboratory result messages, however, frequently lack critical clinical and demographic data needed for surveillance.

While case reporting from clinical care to Public Health Agencies is considered to be a core public health function, its electronic implementation has been slow to advance nationally because of a number of challenges. Laws requiring the reporting of infectious and non-infectious conditions are written individually by each public health jurisdiction. Geographic differences in condition prevalence and other jurisdictional variations have created a complex array of reporting expectations making it difficult for providers to know when, where, and what to report. Healthcare providers, for their part, have been historically inconsistent in reporting from clinical care by any process. For example, a recent CDC study indicated that of the cases of Lyme disease recorded as a clinical diagnosis in clinical care, only about one out of ten are reported to the appropriate PHA. [2]

Case reports are important for tracking disease trends at the Local, State and National levels, but also serve to feed surveillance and outbreak management systems that support the investigation and management of individual cases and outbreaks in routine and emergent public health situations. State, Local and Territorial PHAs are authorized by law to receive identifiable case data to enable these activities.

Previous efforts to develop standards for the exchange of case data between clinical care and public health have been challenged by inter-organizational exchange issues. These issues include efforts to develop numerous implementation guides to accommodate individual conditions and efforts to try to harmonize different jurisdictional reporting nuances and program specific data into one consolidated data specification.

Now, Stage 3 of the CMS EHR Incentive Program (Meaningful Use) program has identified electronic public health case reporting as an option for clinical reporters to meet Meaningful Use criteria. A goal of this implementation guide is to contribute to future certification criteria to ensure that consistent, comparable case reports are received by Public Health Agencies and that a consistent, common eICR can be constructed by EHR vendors and clinical care providers regardless of the jurisdictions in which they must report.

This eICR IG builds on experience, specifications and lessons learned from the previous releases of the HL7 Implementation Guide for CDA Release 2: Public Health Case Reporting; The ONC S&I Framework Public Health Case Reporting Initiative (PHRI); the Council of State and Territorial Epidemiologists (CSTE) "Minimum EHR Data for an Electronic Initial Case Report (eICR)"; work done by CSTE and CDC on the Reportable Conditions Knowledge Management System (RCKMS); and the Association of State and Territorial Health Officials (ASTHO), Association of Public Health Laboratories (APHL), and the CDC work on trigger codes for reportable conditions as part of the Public Health Community Platform (PHCP).[3]

1.5 Scope of the Implementation Guide

The following areas are In Scope for this IG:

- The data elements to be retrieved from the EHR to produce the eICR;
- The specification of an eICR;
- The structure of the eICR in HL7 CDA R2 format;

[2] http://www.cdc.gov/media/releases/2013/p0819-lyme-disease.html

[3] www.thephcp.org

- A description of the stakeholders and actors for each public health reporting User Story;
- The definition of a standard exchange format including structure and content (i.e., vocabulary); and
- Identification of the full requirements to generate reports from EHR systems (in all clinical settings where EHR data is used for reporting purposes, e.g., inpatient, outpatient, emergency room, urgent care) to public health agencies (Note: reports may include administrative, laboratory, pharmacy and/or other information imported from separate systems into the EHR).

The following areas are Out of Scope for this IG:

- The definition, specification, format, and vocabularies used for trigger codes used to initiate the sending of an eICR;
- The specifications for supplemental data associated with a report of a reportable condition;
- The specific methods for providers to transmit eICRs to Public Health Agencies (PHAs). Some of these are described in this IG for context purposes only;
- The methods for PHAs to receive and process eICRs;
- The specification and methods for sending a "reportability response" or other information from the PHA to clinical care;
- The specifications for PHAs to notify the Centers for Disease Control and Prevention of nationally notifiable diseases;
- The definition of specifications and guidelines on reportable event criteria (e.g., defining reportable conditions) – this implementation guide will enable healthcare providers to submit an initial case report, but will not define all the reporting criteria or all potential elements that a jurisdiction may want in a complete report;
- The definition of automated 'business rules' to identify potential reportable events – this implementation guide will enable healthcare providers to submit a report but will not describe the criteria or business rules to identify when such an eICR should be sent;
- The description of the process for healthcare providers to add information into an EHR or auxiliary system;
- The description of the process for public health agencies to perform follow-up activities, including case monitoring;
- The definition of specifications and guidelines for reporting by means other than the transmission of an electronic message or document (e.g., telephone voice, manual web-entry and mailed or faxed information);
- The description of any additional or extensive bi-directional communication between a PHA and a healthcare provider beyond the sending of an eICR;
- The identification of security requirements, methodologies, procedures, and/or protocols; and
- The identification of information and data stewardship practices and policies.

1.6 Current Project

This *HL7 Implementation Guide for CDA® Release 2: HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2, Standard for Trial Use Release 1.1* specification was developed and produced by the HL7 Public Health and Emergency Response Workgroup and co-sponsored by the HL7 Structured Documents Workgroup. It is an update to the *HL7 Implementation Guide for CDA® Release 2: HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2, Standard for Trial Use Release 1*.

The current project contains updates to allow for inclusion of the following information in an eICR instance:

- Flagging of the reportable condition trigger code(s) (RCTC) that initiated the creation/send of the eICR.
- Identification of the reportable condition trigger code table (value set) (RCTC table) used.
- Identification of the RCTC table version
    - The automated initiation of electronic Initial Case Reports is dependent on EHR implementers having a list of codes related to reportable diseases that can be easily matched against relevant patient record data. Some of these trigger codes are intended to be matched against recorded diagnoses. Some are intended to be matched against lab results and some against lab test names when the test name is what identifies a reportable condition. There are also circumstances for conditions that are reportable even when only suspected, where matching against lab orders and even procedure orders may be necessary.

      This electronic Initial Case Report implementation guide now asks for the recording of the specific trigger codes and the trigger code table version (sometimes called the Reportable Condition Trigger Code tables) that were used to initiate the transmission of an initial case report. Depending on the method of EHR initiation there may be one or more than one trigger code that matched and will be recorded. The trigger code table version is important to subsequent processing of received case reports and to identifying needs to update the trigger code table that is being used. The latter can be particularly important when new trigger codes have been added in response to a public health emergency.
- Laboratory test orders
- Travel history
- Exposures to environmental and communicable disease threats through travel play an important role in many emergent public health events and have a significant impact on routine reporting as well. For both reasons it is important for public health investigators to receive travel history information about patients. Currently, if travel history is recorded in clinical care it may be saved in narrative form inside of social history or perhaps some other place. It is important that this implementation guide begin to more specifically identify travel history information and begin to structure the storage of these data for use by public health investigators and, at times, by clinical care personnel. The new implementation of travel history in this CDA implementation guide represents a first step at separating out and highlighting the storage of travel history and initial progress at structuring the included data for automated processing at different levels. Patient sex (as opposed to patient gender)

- Flagging of a manually initiated eICR document and recording the reason for the manual initiation.

The current project also seeks to clarify how to represent the following information in structures already present in the eICR IG:

- County
- Laboratory test abnormal interpretation
- Laboratory test status

This CDA R2 IG uses C-CDA R2.1 templates to build the eICR document. Most of the identified eICR data elements are either mapped straight to already existing C-CDA R2.1 templates or to specializations of C-CDA R2.1 templates. One data element (patient sex) is mapped to a draft template from *C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 1* (C-CDA R2.1 CG) and there is one new CDA R2 template (Travel History) that was created specifically for this IG.

1.6.1 Errata or Enhancements

Comments regarding errata or enhancements may be noted on the HL7 DSTU Comments page: http://www.hl7.org/dstucomments/.

1.7 Stakeholders

Table 1: The key stakeholder groups interested in eICR Use Case

Stakeholders	**Description**
Electronic Health Record (EHR) / Electronic Medical Record (EMR)	The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. Source: http://www.himss.org/ASP/topics_ehr.asp. For purposes of this IG, EHR can also be interpreted to refer to applications that some vendors may call an Electronic Medical Record (EMR).
Healthcare Provider	Any supplier of a healthcare service, i.e., a person or organization that furnishes, bills, or is paid for healthcare in the normal course of business. Includes physicians and healthcare provider staff, as well as ancillary healthcare personnel (e.g., laboratory personnel).
Health IT Vendor	A vendor or supplier is a company/consortium that provides health information technology products and/or services, in this case, for supporting health or healthcare.

Stakeholders	Description
Intermediary System	System that sits between EHR systems and Public Health Information Systems to facilitate exchange and routing of messages. Examples: • Health Information Exchange (HIE) Organizations (HIEs) - Organizations, including state Designated Entities for Health Information Exchange, as well as other organizations, that manage health information exchange among different corporate entities. Includes Regional Health Information Organizations (RHIOs). • Public Health Community Platform (PHCP) Integration Engine • An application that receives messages from the EHR system and parses, and routes messages to a PHA or public health decision support.
Laboratory	The laboratory is a producer of laboratory test results (filler or, at times, placer of a laboratory order).
Laboratory Information System (LIS)	An application to streamline the management of laboratory processes including data collection, workflow management, and report generation. May provide an automatic interface to laboratory analytical instruments to transfer verified results to nurse stations, chart carts, and remote physician offices. Also referred to as a Laboratory Information Management System.
Public Health Agency (PHA)	For the purposes of this IG, a PHA is a governmental entity at the federal, state, territorial, local or tribal level that is legally entitled to establish public health case reporting requirements and receive case reports.
Public Health Decision Support (PHDS)	For the purposes on this IG, PHDS provides clinicians, staff and public health practitioners with knowledge about reporting cases to public health and information about the condition that has been identified. Examples include the Reportable Conditions Knowledge Management System (RCKMS), the Notifiable Condition Detector (NCD), and Electronic Support for Public Health (ESP).
Public Health System	Jurisdictional information systems that may, among other things, receive public health case reports.
Standards Development Organization	An organization that identifies the need for, locates interested parties, and writes specifications that all parties in a particular field of human endeavor can use to their mutual benefit. For the purpose of this document, the field is health or health interoperability and recognition by the American National Standards Institute (ANSI) or the International Standards Organization (ISO) is accepted as evidence that a particular organization is a SDO.

1.8 Future Work / Relationships to Other Projects / Standards

Establishing an HL7 CDA R2 standard implementation guide for an eICR that can be used by all jurisdictions and all conditions is a critical step in advancing the electronic implementation of case reporting between EHRs and Public Health Agencies. There are also other parts of the

clinical care – public health workflow that need consideration when this has been accomplished.

1. Usage guidance and a specification for the communication of trigger codes, e.g. from public health to a provider's EHR system. The specification will include the metadata for all the data values and other guidance needed for sending initial public health report.
2. The Association of Public Health Laboratories (APHL) working with the Association of State and Territorial Health Officials (ASTHO) and the Council of State and Territorial Epidemiologists (CSTE) have developed a draft list of reportable condition trigger codes that EHR vendors can implement to identify relevant clinical diagnoses, laboratory results and some orders. This trigger code list will continue to be developed and maintained in an ongoing way outside of HL7. The current table of codes can be found in PHIN VADS under the Hot Topics for Reportable Conditions Trigger Codes (RCTC).
3. A specification for return communication from the PHA to clinical care, specific to the patient in question, and potentially including information about that condition in that community. In addition to the specifics of the initial case report, such a " reportability response" could contain information such as whether the condition is definitively reportable in that jurisdiction, if there are additional data needed to definitively determine reportability, links to the full reporting requirements in that jurisdiction, links to forms for the input of supplemental data desired for that condition, information about who to contact in the PHA if there are issues to work through via other means, and potentially other information, as needed for public health activities.
4. Specifications need to be developed for PHAs to create and communicate computable and interoperable alerts for consumption by EHRs to render to their clinical users. PHA alerting today is typically generalized and may relate to multiple suspicious cases, environmental events, or other important public health information important for clinical care providers. Providing an interoperability standard for communicating these alerts could enable PH alerts viewable by clinical staff from within an EHR, as well as be computable and queryable. This alerting area may be in scope for other public health projects.
5. On receiving an eICR, PHA personnel may use the information contained therein as a basis for further investigation, to seek more information from clinical care or from a health information exchange, and to close the case or otherwise manage the case and the case status. The ONC Structured Data Capture (SDC) initiative standard may be helpful with providing forms for inputting supplemental information, but further domain analysis and implementation guide work may be needed in these areas as well.
6. With the advent of HL7 FHIR, there will be needs to also map data elements to FHIR, to possibly develop new FHIR resources, and/or FHIR profiles for the eICR. This work will proceed as part of this project by working from relevant data elements in the CSTE Task Force report and the eICR IG.
7. For the complete public health reporting continuum, two additional reporting mechanisms are important for consideration in future related work; reporting between public health jurisdictions or Public Health to Public Health reporting, and Public Health Case Notification.

In some instances, investigations may be started in one jurisdiction and then transferred to another jurisdiction. This is often due to a report being made based on a provider location or hospital location because the patient's residence was unknown at the time of report or because of the reporting rules within a specific jurisdiction. This is regular process that jurisdictions

routinely complete; often as a manual process. Being able to transfer cases and associated investigation information to the appropriate jurisdiction electronically would help make the reporting process more efficient and may provide the necessary information for more timely and accurate public health intervention.

Additionally, some reportable conditions identified by the State and other Public Health Agencies are also notifiable. The CSTE and CDC determine the notifiable conditions, for which there is the need to send notifications to the CDC. Characteristically, there have been times where individual disease and other public health programs have used different data elements for seemingly similar content. There are instances where different Public Health Agencies use different data elements names and definitions, typically because of conditions that were made reportable in one or more PHAs before the CSTE and CDC made them notifiable. Having standardized an eICR, and with appropriate support, it would be valuable for HL7 to convene all of the involved parties in a neutral setting to establish common standards for the FHIR resources and profiles for condition-specific data as well.

1.9 Contents of the Package

The following files comprise this implementation guide package:

Table 2: Contents of the Package

Filename	Description	Standards Applicability: Normative	Standards Applicability: Informative
CDAR2_IG_PHCASERPT_R2_STU1.1_2016DEC_ Vol1_Introductory_Material.docx	Implementation Guide Introductory Material	Chapter 1 Chapter 4 Chapter 5 Appendix A Appendix B Appendix C	Chapter 3 Chapter 6
CDAR2_IG_PHCASERPT_R2_STU1.1_2016DEC_ Vol 2_Templates_and_Supporting_Material.docx	Implementation Guide Template Library and Supporting Material	Templates Appendixes	Examples
CDAR2_IG_PHCASERPT_R2_STU1.1_2016DEC_ SAMPLE.xml CDAR2_IG_PHCASERPT_R2_STU1.1_2016DEC_ SAMPLE_MANUAL.xml	Automatically initiated eICR Sample file Manually initiated eICR Sample File	n/a	Sample file
GForge link: CDA Schema	CDA Schema	n/a	CDA Schema
GForge link: PHCASERPT eIC GForge GForge SVN url: http://gforge.hl7.org/svn/pher/trunk/PHCASERPT_eICR/	Schematron files GForge account required. See: GForge SVN Access Info for details.	n/a	Schematron Vocabulary

Note: *Any conflict between informative and normative content should be resolved in favor of the normative specifications.*

2 USE CASE FOR EICR

The scope of this implementation guide is limited to the generation of an eICR from clinical care. However, eICR generation is only one part of the overall electronic case reporting flow. The broader electronic case reporting flow is depicted in the Context Use Case Flow Diagram below, and is also referenced in the Use Case Assumptions, Pre-Conditions and Post-Conditions sections of this chapter. The broader electronic case reporting (eCR) picture is included both to show where eICR fits (the focus for this IG), and to highlight integral components that should be addressed in subsequent IGs or companion guidance to provide adequate support for full eCR implementation.

2.1 Context Use Case Flow Diagram

The diagram below is intended to set the context for the overall flow of eCR, while showing where initiation and creation of the eICR fits within the flow. The context use case flow diagram is intentionally general as it recognizes that:

- the eICR could be manually initiated by a clinician or automatically initiated based on a match of patient data to a code in a set of codes provided by public health;
- could be created and sent from an EHR system; or be
- created in an EHR and sent through a designee of clinical care, such as an HIE,

as shown in swim lane [1] of the context use case flow diagram.

Likewise, the eICR could be:

- received directly by the PHA; or by an
- intermediary for the PHA, such as the Public Health Community Platform (PHCP) or an HIE,

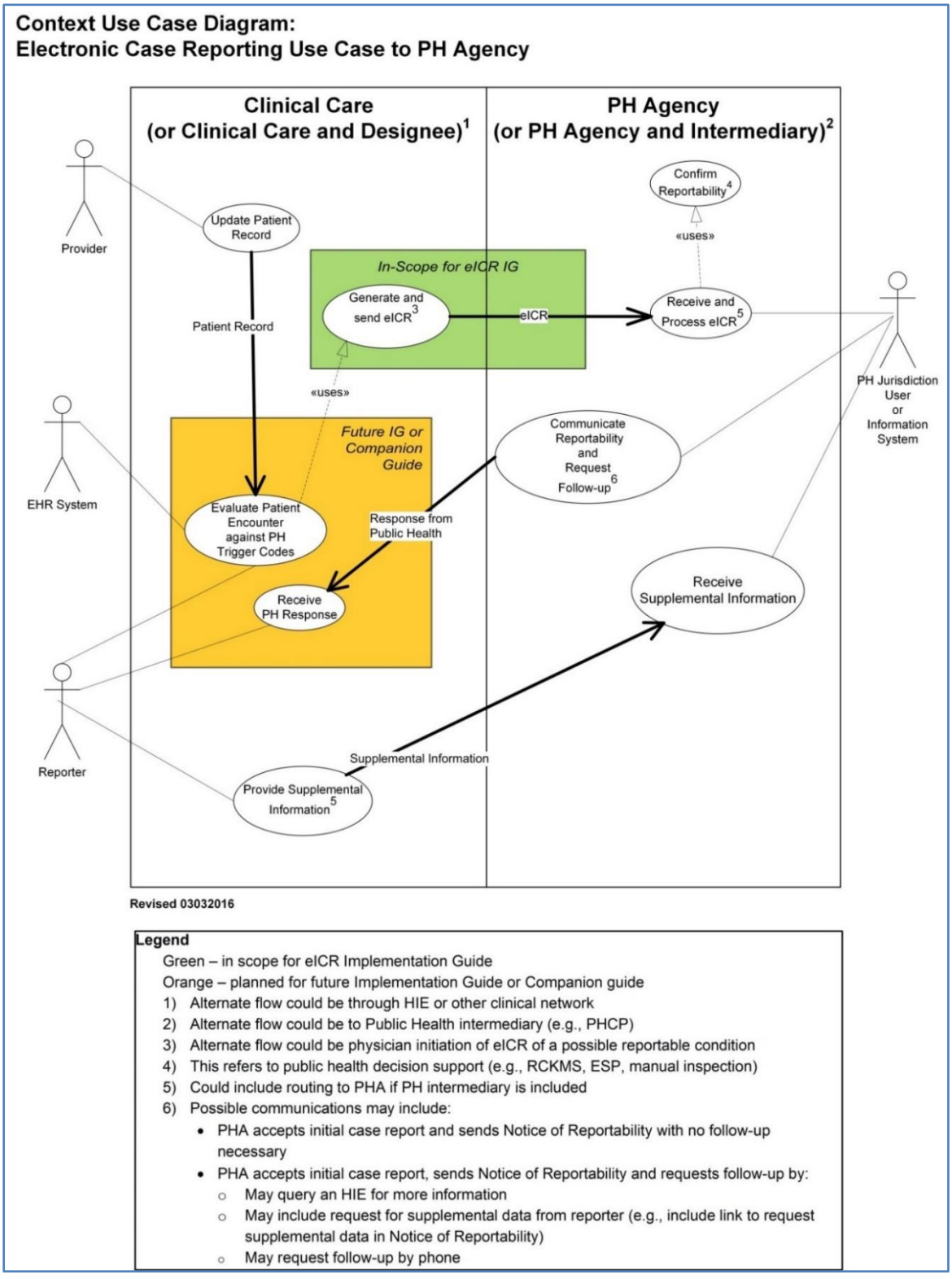
as shown in swim lane [2] of the context use case flow diagram.

Confirm Reportability (context use case flow diagram [4]) is a function that operates against the eICR once received by the PHA (or its intermediary). Its role is to determine if the report meets jurisdictional reporting requirements and to which jurisdiction(s) the report should be sent. Again, in keeping with the general depiction of the eCR flow, the confirmation of reportability could be met by:

- a centralized but jurisdiction specific decision support service such as RCKMS;
- a localized decision support service such as ESP; or

using manual inspection at a jurisdiction in the absence of an automated approach.

Figure 1: Context Use Case Diagram



2.2 Use Case Assumptions

- Patient-level clinical information is entered, imported, or accessed by a healthcare provider using an EHR system.
- Broadly-acceptable security and transport protocols, patient identification methodology, privacy and security procedures, coding, vocabulary, and normalization standards exist and are in use by the EHR system and PHA system.
- The EHR system contains or has access to all relevant information and data (e.g., demographic, clinical, laboratory, pharmacy) to generate a complete and accurate eICR in accordance with requirements described in this implementation guide.
- Appropriate data and information stewardship practices are adopted by exchange partners.
- Network and policy infrastructure exist to enable consistent, appropriate, and accurate information exchange across exchange partners.
- The EHR system may be a single stand-alone system or based upon a component-based architecture. The EHR may interface with other systems that are used to help create, populate or transmit the report to public health or its intermediary.
- The PHA system and/or its intermediary system is in place, is capable of receiving and consuming the report, and receives the report in a standardized structured format.
    - These information systems may be a single stand-alone system or be component based systems used to receive, process, store or archive, as appropriate, the report for review and/or analysis.
- For automated reporting, there is a common standard set of codes used to automatically match against (i.e., trigger codes) information in a patient encounter to initiate the creation and sending of an eICR from all EHR systems. Initial electronic case report documents can also be manually initiated.
- There is a standard structure and set of data elements for the eICR, defined by this IG, that is accepted by all jurisdictions, for all conditions.
- The EHR system is capable of sending the eICR to a PHA system or its intermediary system.
- Confirmation of Reportability will be done by public health decision support outside of the EHR/clinical care system.
    - Public Health (PH) decision support can, at times, handle the variation in requirements for reporting that exist across local, state, tribal, and territorial boundaries.
- The intermediary system HIE, if used, is responsible for passing the acknowledgement from the Public Health Agency Information system to the EHR system; the intermediary system may send separate acknowledgements, but these are not considered the authoritative acknowledgement.

2.3 Pre-Conditions

The following have occurred:

- An authoritative set of reportable condition trigger codes, as provided and defined by PH (available at PHIN VADS RCTC), is maintained and used within the EHR system.
- The creation of an eICR is initiated by one of two methods:
    - An automated match of information in a patient record for an encounter to a set of trigger codes within the EHR; or
    - Manual initiation of the creation of an electronic report to public health by a provider.
- The EHR system populates/generates a report using all appropriate information (e.g., data elements and terminology) for the eICR.
- The receiving system receives and processes the eICR electronically (transmission by fax does not qualify).
    - The receiving system electronically groups multiple eICRs sent from one encounter when multiple trigger code events are matched (e.g. a laboratory result of a reportable condition saved in EHR and clinical diagnosis of reportable condition saved in an EHR problem list).

2.4 Post-Conditions

- The PHA system and/or its intermediary system has received the eICR.
- eICRs are grouped and de-duplicated by receiving system(s).
- A record of an eICR sent from the EHR to the public health agency is stored in a log within the authoring system at the EHR.
- A record of receipt of the eICR is recorded in a log, in the PHA system and/or its intermediary system.

2.5 Actors and Roles

Table 3: The actors and a description of their roles are included in the table below

Actor	Role
Provider	• A person in clinical care organization that updates information in the EHR System
EHR System (healthcare provider system)	• Collect, receive, and/or store data on a patient record • Consume and maintain trigger codes • Match trigger code and generate eICR • Create report and transport to intermediary system or appropriate PHA
Reporter	• A person in clinical care organization that is responsible for reporting to public health
Public Health Agency System	• Receive report from EHR system or intermediary
PH Jurisdiction User	• The person in a public health agency that uses the information contained in the PHA system
Clinical Care (or Clinical Care and Designee)	• Implementer and user or EHR System; or • As designee of clinical care (e.g., HIEs): ○ Receive eICR from EHR system and send to Intermediary or PHA system
Public Health Agency (or PHA and Intermediary)	• Recipient of eICR from EHR system or clinical care designee • Confirmer of reportability • And if at PH intermediary, sender of eICR to PHA system

2.6 Scenarios for Reporting an eICR to Public Health

A patient presents to a healthcare provider for a clinical examination. The healthcare provider performs the clinical examination and may record a clinical diagnosis or order a laboratory test consistent with the findings. Additionally, a laboratory test result may be returned for that patient's clinical encounter.

The generation of an eICR may be initiated by a variety of methods based on the clinical documentation and/or clinical impression. This patient encounter could be evaluated against a set of trigger codes (including SNOMED CT, ICD-10, and LOINC) that are locally implemented within the EHR system. The trigger codes are designed to identify reportable conditions. In some circumstances, secondary analysis or inspection may be needed to confirm reportability. A diagnosis, laboratory order (at times, based on suspicion of a condition), laboratory test or laboratory result code is matched with the trigger codes, and an eICR is generated and sent to a PHA. The clinical provider could also manually initiate the generation and sending of the eICR.

The eICR contains the data elements necessary to initiate a public health investigation or other appropriate public health action.

The eICR is received by one or more appropriate PHAs the eICR is evaluated using public health decision support and a reportability response is returned to the sending EHR system, inclusive of the public health decision support results. The reportability response includes the

confirmation of reportability, information about the responsible public health jurisdiction, and over time, a request for supplemental information about the event if needed and/or information about the status of disease in the community.

By introducing automated public health reporting support, providers will be able to focus on the immediately reportable conditions that still require the provider to telephone the appropriate PHA to initiate a public health investigation.

Narrative with Example:

A mother brings her 6 year old child, Patient A, to Dr. B at Facility C after several days of fever and a progressive rash starting on the face and spreading to the trunk. Patient A presents to Dr. B, practicing at Facility C, with symptoms consistent with varicella infection. After completing the clinical examination, Dr. B records a clinical diagnosis of varicella in the patient's problem list of the patient's record. This patient encounter is evaluated against a set of trigger codes for public health reportable conditions that have been implemented within the EHR system at Facility C. Upon matching the clinical diagnosis of varicella to the trigger codes an eICR is generated and sent to the PHA with authority over Facility C (or an Intermediary System designated by the PHA to receive reports on its behalf).

The trigger codes are designed to match patient encounters that are presumed to be reportable. A public health decision support tool may be used to confirm the reportability of the case from the EHR system at Facility C. The decision support tool utilizes jurisdictionally determined rules and identifies that a clinical diagnosis of varicella is reportable in the public health jurisdiction, a reportability response is provided to the EHR system at Facility C. The eICR is integrated into the PHA's surveillance system for follow-up by a public health investigator. The investigator may contact Patient A to identify close contacts and verify immunity. The public health investigator may also contact Dr. B to follow-up on clinical findings.

Alternative – Public Health Intermediary

The PHA may employ an intermediary's decision support tool to receive the eICR and confirm its reportability. This intermediary would determine reportability based on the location of the healthcare facility, laboratory and/or patient's residence and the correct PHA to which to route the eICR. Pertinent information includes patient address and facility location to determine the jurisdiction with authority to receive this information. The PHA determines whether or not an intermediary will be used.

Narrative with Public Health Intermediary

A patient presents to a healthcare provider for a clinical examination. The healthcare provider performs the clinical examination and may record a differential clinical diagnosis or order a laboratory test consistent with the findings. Additionally, a laboratory test result may be returned for that patient's clinical encounter. This patient encounter is evaluated against a set of trigger codes that are locally implemented within the EHR system. The trigger codes are designed to identify reportable conditions. In some circumstances, secondary analysis or inspection may be needed to confirm reportability. A diagnosis, laboratory order (at times, based on suspicion of a condition), laboratory test, or a laboratory result code is matched with the trigger codes, and an eICR is generated and sent to a centralized public health cloud-based intermediary designated by the PHA.

The intermediary receives the eICR from the EHR system, evaluates the document against centrally hosted public health decision logic to determine the potential public health reportability based on the facility, provider, and/or patient address and patient encounter

characteristics. The intermediary will route the eICR to the correct PHA consistent with the results of the public health decision support.

A reportability response inclusive of the results of the public health decision support will be routed back to the sending EHR system.

The eICR is received by one or more appropriate PHAs based on the business rules administered by the intermediary. The receiving PHA may contact the sending facility or provider for additional follow-up information pertinent to a public health investigation. This follow-up could be multi-modal including utilizing a structured data capture form, a phone call, or a query through an HIE.

Alternative - Manually Initiated eICRs

The clinical provider may manually initiate the sending of the eICR if the provider suspects that the patient has a condition of public health interest. This ability to manually initiate an eICR is important for patient encounters with non-specific symptomology that may not otherwise be automated by triggers. Business rules in any public health reporting decision support tool should be able to differentiate between a manually initiated eICR and one automated from triggers. This will allow public health to triage these reports differently with decision support and investigation initiation.

3 CDA R2 BACKGROUND

CDA R2 is "… a document markup standard that specifies the structure and semantics of 'clinical documents' for the purpose of exchange" [CDA R2, Section 1.1][4]. Clinical documents, according to CDA R2, have the following characteristics:

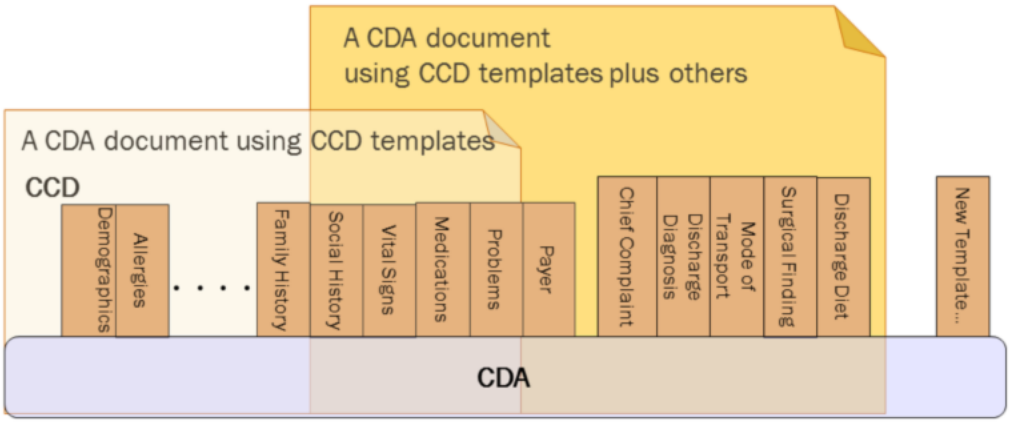
- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

CDA R2 defines a header for classification and management and a document body that carries the clinical record. While the header metadata are prescriptive and designed for consistency across all instances, the body is highly generic, leaving the designation of semantic requirements to implementation.

3.1 Templated CDA R2

CDA R2 can be constrained by mechanisms defined in the "Refinement and Localization"[5] section of the *HL7 Version 3 Interoperability Standards*. The mechanism most commonly used to constrain CDA R2 is referred to as a "CDA template." The "templated CDA" approach uses a library of modular CDA R2 template definitions. Templates can be reused across any number of CDA R2 document types, as shown in the following figure. Each template meets a defined purpose. Templates are managed over time through versioning. A template version is a specific set of conformance constraints designed to meet the template's purpose.

Figure 2: Templated CDA R2



There are many kinds of templates that might be created. Among them, the most common are:

[4] *HL7 CDA Release 2.* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

[5] http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm

Document-level templates: These templates constrain fields in the CDA R2 header, and define containment relationships to CDA R2 sections. For example, a History and Physical document-level template might require that the patient's name be present, and that the document contain a Physical Exam section.

Section-level templates: These templates constrain fields in the CDA R2 section, and define containment relationships to CDA R2 entries. For example, a Physical Exam section-level template might require that the section/code be fixed to a particular LOINC code, and that the section contains a Systolic Blood Pressure observation.

Entry-level templates: These templates constrain the CDA R2 clinical statement model in accordance with real-world observations and acts. For example, a Systolic Blood Pressure entry-level template defines how the CDA R2 Observation class is constrained (how to populate observation/code, how to populate observation/value, etc.) to represent the notion of a systolic blood pressure.

Other templates: Templates that exist to establish a set of constraints that are reused in the CDA R2 document. These other templates are only used within another template, rather than on their own as a complete clinical statement. For example, US Realm Date and Time (DTM.US.FIELDED) includes a set of common constraints for recording time. This template is referenced several times with other templates used in the implementation guide. They reduce the need to repeat constraints in templates that use the common set.

A CDA R2 implementation guide (such as this one) includes references to those template versions that are applicable.

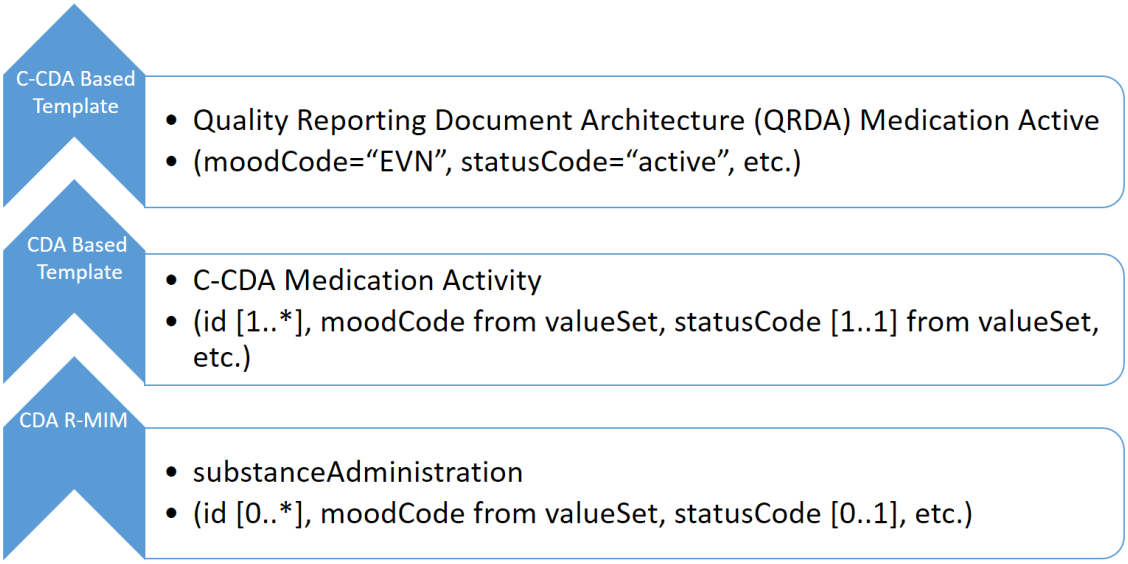
Regarding implementation, a CDA R2 instance populates the template identifier (`templateId`) field where it wants to assert conformance to a given template version. On the receiving side, the recipient can then not only test the instance for conformance against the CDA R2 Extensible Markup Language (XML) schema, but also test the instance for conformance against asserted templates.

3.1.1 Further Constraining Existing Templates

A CDA template is a set of conformance constraints on either the base CDA model (CDA Refined Reference Information Model or R-MIM) or another CDA template (such as an existing C-CDA R2.1 templates). A new template is created that contains all the constraints of the base template and which further constrains that template. Constraints can only be tightened, not loosened. These further constraints can, for example, tighten a SHOULD to a SHALL or change [0..*] to [1..1]. Constraints can also be applied to vocabulary, for example, binding to a specific code system or value set or only allowing the use of a single specific code (single value binding).

The following figure illustrates this "layering" of constraints starting from the most general (CDA R-MIM) at the bottom to the most specific (C-CDA Based Template) at the top. Each level

conforms to the constraints of the level below it and adds a further set of conformance constraints to satisfy a particular use case:



The new template is fully conformant to the template it is based on, and contains the templateId of that template, as well as its own templateId. The following figure is an example of the presence of two templateIds to indicate that this template is asserting conformance to both templates:

Figure 3: Initial Case Report Trigger Code Problem Observation Example

```
<observation classCode="OBS" moodCode="EVN">
    ...

    <!-- [C-CDA R2.1] Problem Observation (V3) -->
    <templateId extension="2015-08-01" root="2.16.840.1.113883.10.20.22.4.4" />
    <!-- [eICR R2 STU1.1 Problem Observation (RCTC) -->
    <templateId extension="2016-12-01" root="2.16.840.1.113883.10.20.15.2.3.3" />
    …
</observation>
```

3.1.2 Status of a Template Version

Each version of a template has a status. For example, a template version can be draft, active, or deprecated, etc. The HL7 Templates DSTU describes the various status states that may apply to a template version over the course of its lifecycle. Each version of a template has an associated status. Thus, one version of a template may be deprecated, while a newer version of that template may be draft or active.

4 USING THIS IMPLEMENTATION GUIDE

This chapter describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA R2 templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this guide.

4.1 Conformance Conventions Used in This Guide

4.1.1 Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from Trifolia Workbench, a template repository.[6] An algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:86-7345). The digits in the conformance number before the hyphen identify which implementation guide the template belongs to and the number after the hyphen is unique to the owning implementation guide. Together, these two numbers uniquely identify each constraint. These identifiers are persistent but not sequential. Conformance numbers in this guide associated with a conformance statement that is carried forward from a previous version of this guide will carry the same conformance number from the previous version. This is true even if the previous conformance statement has been edited. If a conformance statement is entirely new it will have a new conformance number.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the object `identifier (OID)` or `uniform resource name (URN)`, and whether the template is open or closed. The `identifier OID` is the `templateId/@root value`; all `templateIds` have an `@root` value. Versioned templates also have an `@extension` value, which is a date identifying the version of this template; such templates are identified by `URN` and the HL7 version (`urn:hl7ii`). The `URN` identifier includes both the `@root` and `@extension` value for the `templateId` (for example, `identifier urn:hl7ii:2.16.840.1.113883.10.20.5.5.41:2014-06-09`).

Each section and entry template in Volume 2 of this guide includes a context table. The "Contained By" column indicates which templates use this template, and if the template is optional or required in the containing template. The "Contains" column indicates any templates that this template uses.

Table 4: Initial Case Report Trigger Code Problem Observation Contexts

Contained By:	Contains:
Encounter Diagnosis (V3) (optional) Problem Concern Act (V3) (optional)	

Each entry template also includes a constraints overview table to summarize the constraints in the template.

[6] Trifolia Workbench, https://trifolia.lantanagroup.com/

Table 5: Initial Case Report Trigger Code Lab Test Order Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.4:2016-12-01)					
@classCode	1..1	SHALL		3284-317	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		3284-318	urn:oid:2.16.840.1.113883.11.20.9.25 (Planned moodCode (Observation))
templateId	1..1	SHALL		3284-311	
@root	1..1	SHALL		3284-319	2.16.840.1.113883.10.20.15.2.3.4
@extension	1..1	SHALL		3284-320	2016-12-01
id	1..*	SHALL		3284-321	
code	1..1	SHALL		3284-325	urn:oid:2.16.840.1.113883.6.1 (LOINC)
@code	1..1	SHALL		3284-336	urn:oid:2.16.840.1.113762.1.4.1146.166 (Trigger code for laboratory test orders (RCTC subset))
@sdtc:valueSet	1..1	SHALL		3284-337	2.16.840.1.114222.4.11.7508
@sdtc:valueSetVersion	1..1	SHALL		3284-338	

The expression “such that it” at the end of one conformance statement links that conformance statement to the following subordinate conformance statement to further constrain the first conformance statement. To understand the full effect of this conformance construct, the two conformances must be considered as a single compound requirement. The subordinate conformance statement functions as a subordinate clause (like a "where" clause), which is being applied on the first conformance statement.

The following example shows a compound conformance statement made up of two conformance statements joined by a "such that it" clause. The effect of this syntax can be interpreted as a "where" clause. Thus...

1. **SHALL** contain exactly one [1..1] **templateId** 81-7899) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.31" 81-10487).

...is understood as:

> This template **SHALL** contain exactly one [1..1] **templateId** where it contains exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.31".

This means that you must have a template id with **@root**="2.16.840.1.113883.10.20.22.4.31", but you can also have other template ids with different valued attributes.

The following figure shows a typical template’s set of constraints presented in this guide.

Figure 4: Constraints Format Example

Initial Case Report Trigger Code Lab Test Order

`[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.4:2016-12-01 (open)]`

Draft as part of Public Health Case Report, Release 1, STU Release 1.1 - US Realm

...

1. Conforms to **Planned Observation (V2)** template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.44:2014-06-09).
2. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 **STATIC**) (CONF:3284-317).
3. **SHALL** contain exactly one [1..1] **@moodCode**, which **SHALL** be selected from ValueSet **Planned moodCode (Observation)** urn:oid:2.16.840.1.113883.11.20.9.25 **STATIC** 2011-09-30 (CONF:3284-318).
4. **SHALL** contain exactly one [1..1] **templateId** (CONF:3284-311) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.15.2.3.4" (CONF:3284-319).
   b. **SHALL** contain exactly one [1..1] **@extension**="2016-12-01" (CONF:3284-320).
5. **SHALL** contain at least one [1..*] **id** (CONF:3284-321).
   Note: Placer order number
6. **SHALL** contain exactly one [1..1] **code**, which **SHOULD** be selected from CodeSystem LOINC (urn:oid:2.16.840.1.113883.6.1) (CONF:3284-325).
   Note: Lab order code
   a. This code **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be selected from ValueSet **Trigger code for laboratory test orders (RCTC subset)** urn:oid:2.16.840.1.113762.1.4.1146.166 **DYNAMIC** (CONF:3284-336).
   b. This code **SHALL** contain exactly one [1..1] **@sdtc:valueSet**="2.16.840.1.114222.4.11.7508" (CONF:3284-337).
   c. This code **SHALL** contain exactly one [1..1] **@sdtc:valueSetVersion** (CONF:3284-338).

The next chapters describe specific aspects of conformance statements—open vs. closed statements, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors (see also eICR IG Specific Conformance Guidance).

4.1.2 Template Versioning

Under the "templated CDA" approach a new implementation guide can use existing CDA R2 templates from previously published implementation guides. A new version of an existing implementation guide reuses templates from either the previous version or another published IG. During the ballot and update phases, templates carry the designation "Published" to indicate the template is unchanged from the previous version or other IG or "Draft" to indicate a new or revised template. Substantial revisions to previously published templates are indicated by the version number (V2, V3, etc.) in all phases: ballot, update, and published guides.

If there are no substantive changes to a template that has been successfully published, the template will carry the same `templateId/@root` (`identifier oid`) and `templateId/@extension` as in the previous implementation guide. (In the case of older templates, the `@extension` attribute will not be present.) During a new ballot or update phase, "Published" is appended to the main heading for the template to indicate that the template cannot be commented on in the ballot or update. The "Published" designation is removed in the final publication versions.

A revised version of a previously published template keeps the same `templateId/@root` as the previous version but is assigned a new `templateId/@extension`. The notation "(Vn)" (V2, V3, etc.) is also added to the template name. Versions are not necessarily forward or backward compatible. A versioning may be due to substantive changes in the template or because a contained template has changed. The "(Vn)" designation is persistent; it appears with that template when it is used in subsequent guides. During a new ballot or update phase, "Draft" is appended to the main heading for the template to indicate that it may be voted on in the ballot or commented on in the update; the "Draft" designation is removed in the final publication versions.

4.1.3 C-CDA R2.1 Assertion of Compatibility with C-CDA R1.1

In addition to the assertion described in Further Constraining Existing Templates, C-CDA R2.1 includes a requirement that all C-CDA R2.1 conformant instances:

- Include a C-CDA R2.1 templateId,
- Additionally, when the C-CDA R2.1 templateId includes an extension, the C-CDA R1.1 template must also be included

By including both templateIds the sending application is asserting conformance with C-CDA R2.1 and C-CDA R1.1.

While this assertion of conformance with C-CDA R2.1 and C-CDA R1.1 is **NOT** a requirement of the eICR IG, it is recommended that:

- If the originating system includes both the versioned and un-versioned templateId, then both these templateIds **SHOULD** be preserved in the eICR document.

The examples and sample file included with this IG illustrate the optional use of the C-CDA R1.1 templateId:

Figure 5: Initial Case Report Trigger Code Problem Observation Example

```
<observation classCode="OBS" moodCode="EVN">
    <!-- [C-CDA R1.1] Problem Observation -->
    <templateId root="2.16.840.1.113883.10.20.22.4.4" />
    <!-- [C-CDA R2.1] Problem Observation (V3) -->
    <templateId extension="2015-08-01" root="2.16.840.1.113883.10.20.22.4.4" />
    <!-- [eICR R2 STU1.1 Problem Observation (RCTC) -->
    <templateId extension="2016-12-01" root="2.16.840.1.113883.10.20.15.2.3.3" />
    …
</observation>
```


4.1.4 Open and Closed Templates

In open templates, all the features of the CDA R2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed and nothing further may be included.

Open templates allow HL7 implementers to develop additional structured content not constrained within this guide. HL7 encourages implementers to bring their use cases forward as candidate requirements to be formalized in a subsequent version of the standard to maximize the use of shared semantics.

4.1.5 Conformance Verbs (Keywords)

The keywords **SHALL, SHOULD, MAY, NEED NOT, SHOULD NOT,** and **SHALL NOT** in this document are to be interpreted as described in the *HL7 Version 3 Publishing Facilitator's Guide.*[7]

SHALL: an absolute requirement

SHALL NOT: an absolute prohibition against inclusion

SHOULD/SHOULD NOT: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course

MAY/NEED NOT: truly optional; can be included or omitted as the author decides with no implications

The keyword "**SHALL**" allows the use of `nullFlavor` unless the requirement is on an attribute or the use of `nullFlavor` is explicitly precluded.

When conformance statements are nested (or have subordinate clauses) the conformance statements are to be read and interpreted in hierarchical order. These hierarchical clauses can be interpreted as "if then, else" clauses. Thus...

a. This structuredBody **SHOULD** contain zero or one [0..1] **component** 1098-29066) such that it
    i. **SHALL** contain exactly one [1..1] **Plan of Treatment Section (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.10:2014-06-09) 1098-29067).

...is understood as:

a. It is recommended (**SHOULD**) that the structureBody contains a component.
    i. **If** the component exists, **then** it must contain a Plan of Treatment Section (V2),
    ii. **else** the component does not exist, and the conformance statement about the Plan of Treatment Section (V2) should be skipped.

In the case where the higher level conformance statement is a **SHALL,** there is no conditional clause. Thus...

b. This structuredBody **SHALL** contain exactly one [1..1] **component** 1098-29086) such that it

[7] HL7, *Version 3 Publishing Facilitator's Guide.* http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm

i. **SHALL** contain exactly one [1..1] **Problem Section (entries required) (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.5.1:2014-06-09) 1098-29087).

...means that the structuredBody is always required to have a component.

4.1.6 Cardinality

The cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format "m...n" where m represents the least and n the most:

0..1 zero or one

1..1 exactly one

1..* at least one

0..* zero or more

1..n at least one and not more than n

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure 6: Constraints Format – only one allowed

1. **SHALL** contain exactly one [1..1] **participant** 2777).
   a. This participant **SHALL** contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) 2230).

In the next figure, the constraint says only one participant "like this" is to be present. Other participant elements are not precluded by this constraint.

Figure 7: Constraints Format – only one like this allowed

1. **SHALL** contain exactly one [1..1] **participant** 2777) such that it
   a. **SHALL** contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) 2230).

4.1.7 Optional and Required with Cardinality

The terms *optional* and *required* describe the *lower* bound of cardinality as follows:

Optional means that the number of allowable occurrences of an element may be 0; the cardinality will be expressed as [0..1] or [0..*] or similar. In these cases, the element may not be present in the instance. Conformances formulated with **MAY** or **SHOULD** are both considered "optional" conformances.

Required means that the number of allowable occurrences of an element must be at least 1; the cardinality will be expressed as `[m..n]` where `m >=1` and `n >=1` for example `[1..1]` or `[1..*]`. In these cases, the element must be present in the instance. Conformance statements formulated with **SHALL** are required conformances. If an element is required but is not known (and would otherwise be omitted if it were optional), the `@nullFlavor` attribute must be used. See Unknown and No Known Information.

4.1.8 Unknown and No Known Information

Here, we provide guidance on representing unknown information. Further details can be found in the HL7 V3 Data Types, Release One specification that accompanies the CDA R2 normative standard. **However, it should be noted that the focus of C-CDA R2.1 is on the unambiguous representation of known data, and that in general, the often subtle nuances of unknown information representation are less relevant to the recipient.**

Many elements in CDA R2 contain a "`@nullFlavor`" attribute, used to indicate an exceptional value. Some flavors of Null are used to indicate that the known information falls outside of value set binding constraints. Not all uses of the `@nullFlavor` attribute are associated with a case where information is unknown. Allowable values for populating the attribute give more details about the reason the information is unknown, as shown in the following example.

Figure 8: nullFlavor Example

```
<birthTime nullFlavor="UNK" />
<!-- Sender does not know the birthTime, but a proper value is
     applicable -->
```

Use null flavors for unknown, required, or optional attributes:

NI	No information. This is the most general and default null flavor.
NA	Not applicable. Known to have no proper value (e.g., last menstrual period for a male).
UNK	Unknown. A proper value is applicable, but is not known.
ASKU	Asked, but not known. Information was sought, but not found (e.g., the patient was asked but did not know).
NAV	Temporarily unavailable. The information is not available, but is expected to be available later.
NASK	Not asked. The patient was not asked.
MSK	There is information on this item available but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information.
OTH	The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).

The list above contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the `nullFlavor` vocabulary domain in the CDA R2 normative edition.[8]

Any **SHALL**, **SHOULD** or **MAY** conformance statement may use `nullFlavor`, unless the `nullFlavor` is explicitly disallowed (e.g., through another conformance statement which includes a **SHALL** conformance for a vocabulary binding to the @code attribute, or through an explicit **SHALL NOT** allow use of `nullFlavor` conformance).

Figure 9: Attribute Required (nullFlavor not allowed)

1. **SHALL** contain exactly one [1..1] `code` 15407).
   a. This `code` **SHALL** contain exactly one [1..1] **@code**="11450-4" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1) 15408).

   or

2. **SHALL** contain exactly one [1..1] **effectiveTime/@value** 5256).

Figure 10: Allowed nullFlavors When Element is Required (with xml examples)

1. **SHALL** contain at least one `[1..*] id`
2. **SHALL** contain exactly one `[1..1] code`
3. **SHALL** contain exactly one `[1..1] effectiveTime`

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    <id nullFlavor="NI"/>
    <code nullFlavor="OTH">
      <originalText>New Grading system</originalText>
    </code>
    <statusCode code="completed"/>
    <effectiveTime nullFlavor="UNK"/>
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

[8] *HL7 CDA Release 2.* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

If a sender wants to state that a piece of information is unknown, the following principles apply:

1. If the sender doesn't know an attribute of an act, that attribute can be null.

Figure 11: Unknown Medication Example

1. **SHALL** contain exactly one `[1..1] code`

```
<entry>
  <text>patient was given a medication but I do not know what it was</text>
  <substanceAdministration moodCode="EVN" classCode="SBADM">
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code nullFlavor="NI"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

2. If the sender doesn't know if an act occurred, the `nullFlavor` is on the act (detail could include specific allergy, drug, etc.).

Figure 12: Unknown Medication Use of Anticoagulant Drug Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" nullFlavor="NI">
    <text>I do not know whether or not patient received an anticoagulant
          drug</text>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="81839001" displayName="anticoagulant drug"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

3. If the sender wants to state "no known", a `negationInd` can be used on the corresponding act (`substanceAdministration`, `Procedure`, etc.)

   Previously, CCD, IHE, and HITSP recommended using specific codes to assert no known content, for example `160244002 No known allergies` or `160245001 No current problems or disability`. Specific codes are still allowed; however, use of these codes is not recommended.

   These next examples illustrate nuances of representing information in coded fields when information is a negative assertion, for example it is not the case that the patient has an allergy or it is not the case that a patient takes a medication. The phrases "no

known allergies" or "no known medications" are typically associated with this type of negative assertion.

Figure 13: No Known Medications Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" negationInd=”true”>
    <text>No known medications</text>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="410942007" displayName="drug or medication"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

Figure 14: Value Known, Code for Value Not Known

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    …
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

Figure 15: Value Completely Unknown

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    …
    <value xsi:type="CD" nullFlavor="UNK"/>
  </observation>
</entry>
```


Figure 16: Value Known, Code in Required Code System Not Known But Code from Another Code System is Known

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    …
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
      <translation code="129742005" displayName="spiculated lesion"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>/>
    </value>
  </observation>
</entry>
```

4.1.9 Vocabulary Conformance

The templates in this document use terms from several code systems. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT® vocabularies.

Note that *in most cases* (see: Trigger Code Templates for exceptions) value-set identifiers (e.g., ValueSet `2.16.840.1.113883.1.11.78 Observation Interpretation (HL7)` **DYNAMIC)** used in the binding definitions of template conformance statements do not appear in the XML instance of a CDA R2 document. The definition of the template must be referenced to determine or validate the vocabulary conformance requirements of the template.

Value-set bindings adhere to HL7 Vocabulary Working Group best practices, and include both an indication of stability and of coding strength for the binding. Value set bindings can be **STATIC**, meaning that they bind to a specified version of a value set, or **DYNAMIC**, meaning that they bind to the most current version of the value set. If a **STATIC** binding is specified, a date **SHALL** be included to indicate the value set version. If a **DYNAMIC** binding is specified, the value set authority and link to the base definition of the value set **SHALL** be included, if available, so implementers can access the current version of the value set. When a vocabulary binding binds to a single code, the stability of the binding is implicitly **STATIC**.

Figure 17: Binding to a Single Code

2. SHALL contain exactly one [1..1] **code** 15403).
  a) This code **SHALL** contain exactly one [1..1] **@code**="11450-4" Problem List 15408).
  b) This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) 31141).

The notation conveys the actual code (`11450-4`), the code's `displayName` (Problem List), the OID of the `codeSystem` from which the code is drawn (2.16.840.1.113883.6.1), and the `codeSystemName` (LOINC).

HL7 Data Types Release 1 requires the `codeSystem` attribute unless the underlying data type is "Coded Simple" or "CS", in which case it is prohibited. The `displayName` and the `codeSystemName` are optional, but recommended, in all cases.

The above example would be properly expressed as follows.

Figure 18: XML Expression of a Single-code Binding

```
<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
      displayName="Problem List"
      codeSystemName="LOINC"/>
```

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the *HL7 V3 Normative Edition 2010*[9] sections on Abstract Data Types and XML Data Types R1.

There is a discrepancy between the HL7 R1 Data Types and this guide in the implementation of translation code versus the original code. The R1 data type requires the original code in the root. The convention agreed upon for this implementation guide specifies a code from the required value set be used in the element and other codes not included in the value set are to be represented in a translation for the element. This discrepancy is resolved in HL7 Data Types R2.

In the next example, the conformant code is SNOMED-CT code 206525008.

Figure 19: Translation Code Example

```
<code code='206525008’
      displayName='neonatal necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'>
   <translation code='NEC-1'
      displayName='necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.19'/>
</code>
```

Value set tables are present below a template, or are referenced if they occur elsewhere in the specification, when there are value set bindings in the template. The value set table provides the value set identifier, a description, and a link to the source of the value set when possible. Ellipses in the last row indicate the value set members shown are examples and the true source must be accessed to see all members.

If a value set binding has a **DYNAMIC** stability, implementers creating a CDA R2 document must go to the location in the Uniform Resource Locator (URL) to check for the most current version of the value set expansion.

[9] *HL7 Version 3 Interoperability Standards,* Normative Edition 2010.
http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010

Figure 20: Example Value Set Table (Language)

Value Set: Language 2.16.840.1.113883.1.11.11526 A value set of codes defined by Internet RFC 4646 (replacing RFC 3066). Please see ISO 639 language code set maintained by Library of Congress for enumeration of language codes. Value Set Source: http://www.ietf.org/rfc/rfc4646.txt			
Code	**Code System**	**Code System OID**	**Print Name**
aa	Language	2.16.840.1.113883.6.121	Afar
ab	Language	2.16.840.1.113883.6.121	Abkhazian
ace	Language	2.16.840.1.113883.6.121	Achinese
ach	Language	2.16.840.1.113883.6.121	Acoli
ada	Language	2.16.840.1.113883.6.121	Adangme
ady	Language	2.16.840.1.113883.6.121	Adyghe; Adygei
ae	Language	2.16.840.1.113883.6.121	Avestan
af	Language	2.16.840.1.113883.6.121	Afrikaans
…			

4.1.10 Containment Relationships

Containment constraints between a section and its entry are indirect in this guide, meaning that where a section asserts containment of an entry, that entry can either be a direct child or a further descendent of that section.

For example, in the following constraint:

1. **SHALL** contain at least one [1..*] **entry** 8647) such that it
    a. **SHALL** contain exactly one [1..1] **Advance Directive Observation** (templateId:2.16.840.1.113883.10.20.22.4.48) 8801).

the Advance Directive Observation can be a direct child of the section (i.e., section/entry/AdvanceDirectiveObservation) or a further descendent of that section (i.e., section/entry/…/AdvanceDirectiveObservation). Either of these are conformant.

All other containment relationships are direct, for example:

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.21" 7928).

The templateId must be a direct child of the section (i.e., section/templateId).

4.1.11 Data Types

All data types used in a CDA R2 document are described in the CDA R2 standard. All attributes of a data type are allowed unless explicitly prohibited by this specification.

4.1.12 Document-Level Templates "Properties" Heading

In Volume 2 of this implementation guide, each document-level template has a "Properties" heading for ease of navigation. The Properties heading is an organizational construct,

underneath which relevant CDA R2 act-relationships and roles are called out as headings in the document.

4.2 XML Conventions Used in This Guide

4.2.1 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation[10] in conformance statements and elsewhere to identify the Extensible Markup Language (XML) elements and attributes within the CDA R2 document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

XPath statements appear in this document in a `monospace font`.

XPath syntax selects nodes from an XML document using a path containing the context of the node(s). The path is constructed from node names and attribute names (prefixed by a '@') and concatenated with a '/' symbol.

Figure 21: XML Document Example

```
<author>
  <assignedAuthor>
  ...
    <code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'
          code='17561000' displayName='Cardiologist' />
  ...
  </assignedAuthor>
</author>
```

In the above example, the `code` attribute of the code could be selected with the XPath expression in the next figure.

Figure 22: XPath Expression Example

```
author/assignedAuthor/code/@code
```

4.2.2 XML Examples and Sample Documents

Extensible Mark-up Language (XML) examples appear in figures in this document in `this monospace font`. XML elements (`code, assignedAuthor`, etc.) and attribute names (`SNOMED CT, 17561000`, etc.) also appear in this `monospace font`. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (. . .) as shown in the example below.

[10] XML Path Language. http://www.w3.org/TR/xpath/

Figure 23: ClinicalDocument Example

```
<ClinicalDocument xmls="urn:h17-org:v3">
  ...
</ClinicalDocument>
```

This publication package includes complete XML sample documents as listed in the Contents of the Package table.

5 EICR IG SPECIFIC CONFORMANCE GUIDANCE

The CDA R2 templates expressed in this specification are grouped according to type: Document, Section, Entry, and Datatype. Templates are arranged alphabetically within type. Each template is presented with a template title followed by template type and object identifier (OID), and a table of hyperlinked nested and encompassing templates.

5.1 Template Types

The majority of templates used in this guide are a reuse or specialization (further constraints added to existing templates) of templates from the *HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1* (C-CDA R2.1).

The electronic Initial Case Report Document (eICR) (V2) template is unique to this guide and establishes the document header for the eICR document type. This header extends the C-CDA R2.1 US Realm Header (V3) document type to include additional administrative and demographic elements unique to the eICR. The eICR header includes a structured document body with references to applicable C-CDA R2.1 section templates.

This guide also includes the Birth Sex Observation template which is part of the *C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 1* (C-CDA R2.1 CG) and Travel History which is a new CDA R2 template.

The C-CDA R2.1 section templates include references to optional C-CDA R2.1 entry templates. Only the templates relevant to eICR have been included in this specification.

5.2 Stand-Alone Templates

For templates added to the current release of this IG, a new template containment referencing technique is being followed. This technique is in development for a future volume of Consolidated CDA that will be called C-CDA Volume 3, and will consist only of optional templates. The approach seeks to lessen the impact of adding new templates to published specifications. Bringing all of C-CDA to ballot requires thousands of work hours on tasks including design, initial development, ballot, ballot reconciliation, and finally publishing. Also, in the past, the impact of adding a new template to an IG has been that a "bubble-up" versioning of all containing templates is required (all templates in the containing hierarchy need to be versioned, up to the top level (document) template). See Template Versioning. This is a burden on both the specification authors and implementers, as many more templates than just the template being authored are affected. By making templates optional, C-CDA Volume 3 can be developed and balloted independently of the rest of C-CDA, resulting in much faster development cycles.

The template containment referencing technique creates new templates as "stand-alone" entities and specifies the application of the template in its own description rather than in the constraints of the containing template(s). As the majority of CDA R2 templates are open templates (see Open and Closed Templates), it is not a requirement that a template explicitly reference a template in order to contain that template.

The following is excerpt from a template definition that demonstrates this method:

Figure 6: Stand-Alone Template Example

Initial Case Report Trigger Code Lab Test Order

```
[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.4:2016-12-
01 (open)]

Draft as part of Public Health Case Report, Release 1, STU Release 1.1 - US
Realm
```

Table 7: Initial Case Report Trigger Code Lab Test Order Contexts

Contained By:	Contains:
Plan of Treatment Section (V2) (optional)	

The Initial Case Report Trigger Code Lab Test Order flags that the observation code is a trigger code contained in the **Reportable Condition Trigger Codes table** - specifically, one of the codes in the Trigger Code for Laboratory Test Orders value set (RCTC subset).

This template is for optional use in the Plan of Treatment Section (V2) contained in an Initial Public Health Case Report Document (eICR) (V2).

…

5.3 Lineage to eICR Domain Analysis Model (DAM)

A brief description is provided for each template which is followed by a numbered list of constraints each followed by a unique conformance identifier. Where appropriate, lineage to the eICR Domain Analysis Model (DAM) is designated with the prefix “Note:” followed by the name of the DAM class and attribute which provide context for the data requirements. For example, the following note documents the lineage from the CDA R2 AssignedEntity.id to the eICR DAM ResponsibleProvider.identifier:

1. This assignedEntity **SHALL** contain at least one [1..*] **id** (CONF:3284-8).
   Note: ResponsibleProvider.identifier

5.4 Trigger Code Templates

Reportable condition trigger codes are contained in the Reportable Condition Trigger Codes (RCTC) table. This table can be downloaded from the Public Health Information Network Vocabulary Access and Distribution System (PhinVads) at the following link: RCTC Table.

The eICR IG contains a set of templates ("trigger code templates") designed to flag the existence of reportable condition trigger codes in diagnoses and ordered/resulted laboratory tests. There

may be more than one trigger code type and more than one trigger code of each type in an eICR CDA Document. The trigger code template are as follows:

- Initial Case Report Trigger Code Problem Observation
  `[urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.3:2016-12-01]`
- Initial Case Report Trigger Code Result Observation
  `[urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.2:2016-12-01]`
- Initial Case Report Trigger Code Lab Test Order
  `[urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.4:2016-12-01]`

The trigger code templates are new eICR IG templates. They are based on C-CDA R2.1 templates and follow the principles described in Further Constraining Existing Templates and Stand-Alone Templates. These templates further constrain C-CDA R2.1 templates as follows:

- Problem Observation (V3) -> Initial Case Report Trigger Code Problem Observation
- Result Observation (V3) -> Initial Case Report Trigger Code Result Observation
- Planned Observation (V2) -> Initial Case Report Trigger Code Lab Test Order

The common constraints added to all trigger code templates are:

- new `templateId` - the presence of the new `templateId` is the flag for a trigger code
- constrain `code/@code` to the RCTC table (value set)
- `code/@sdtc:valueSet` must be present in order to capture the RCTC table OID (2.16.840.1.114222.4.11.7508)
- `code/@sdtc:valueSetVersion` must be present in order to capture the RCTC definition version.

Initial Case Report Trigger Code Problem Observation only:

- constrain `@negationInd` to "false" to ensure a positive assertion

Initial Case Report Trigger Code Result Observation only:

- constrain `statusCode` to either "active" or "completed" to ensure only preliminary or final results
- require a `value` (result)

Initial Case Report Trigger Code Lab Test Order only:

- constrain `observation/@moodCode` to "RQO" to represent an order
- constrain

The following table is an example of one of the new trigger templates - it must conform to all the constraints of the template on which it is based (these constraints are not repeated in the new template's definition) and the new constraints are highlighted:

Table 8: Initial Case Report Trigger Code Problem Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF #	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.3:2016-12-01)					
@classCode	1..1	SHALL		3284-183	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		3284-184	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
@negationInd	1..1	SHALL		3284-296	false
templateId	1..1	SHALL		3284-157	
@root	1..1	SHALL		3284-169	2.16.840.1.113883.10.20.15.2.3.3
@extension	1..1	SHALL		3284-170	2016-12-01
value	1..1	SHALL	CD	3284-160	
@code	1..1	SHALL		3284-176	urn:oid:2.16.840.1.113762.1.4.1146.28 (Trigger code for condition name (RCTC subset))
@sdtc:valueSet	1..1	SHALL		3284-187	2.16.840.1.114222.4.11.7508
@sdtc:valueSetVersion	1..1	SHALL		3284-188	

As stated in Vocabulary Conformance, *in most cases*, value set identifiers (e.g., ValueSet `2.16.840.1.113883.1.11.78 Observation Interpretation`) do not appear in the XML instance of a CDA R2 document.

The exception to this rule is when populating `@sdtc:valueSet` and `@sdtc:valueSetVersion` to reference the Reportable Condition Trigger Code (RCTC) value set, as seen in the following example:

Figure 24: RCTC Value Set Example

```
<code code="11585-7"
    codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC"
    displayName="Bordetella pertussis Ab [Units/volume] in Serum"
    sdtc:valueSet="2.16.840.1.114222.4.11.7508"
    sdtc:valueSetVersion="19/05/2016" />
```

The trigger code templates do not change any existing data. For example, if a problem list is already being sent using C-CDA Problem Observation (V3) templates, this list would stay the

same, with the exception of any trigger diagnoses (the code used for the diagnosis is contained in the RCTC table), which would now be flagged with a new templateId and have the RCTC table OID (2.16.840.1.114222.4.11.7508) recorded in `code/@sdtc:valueSet` and the RCTC definition version (e.g. 19/05/2016) recorded in `code/@sdtc:valueSetVersion`.

5.5 Manually Initiated eICR Documents

In some cases an eICR document may be manually initiated by a provider rather than being automatically initiated by an RCTC trigger code.

When the serviceEvent in the CDA Header is present with a code of "PHC1464: Manually Initiated eICR", this flags that this document is manually initiated.

The reason for the manual initiation is recorded as free text in the Initial Case Report Manual Initiation Reason Observation `[urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.5:2016-12-01]`.

This new eICR IG template is based on the C-CDA R2.1 Problem Observation (V3) template and follows the principles described in Further Constraining Existing Templates and Stand-Alone Templates.

5.6 Null Values and the eICR IG

The constraint of "SHALL" has been applied to the majority of data elements identified in Section CSTE Identified Data Requirements of this specification. This allows the eICR to be transmitted with as much information as is known at the time of the triggering event within the encounter. A "`@nullFlavor`" attribute (such as the most general and default null flavor for no information 'NI') allows the sender to explicitly indicate that the information isn't known or available. See Unknown and No Known Information.

However, there is a small subset of data elements that the Public Health Agency Information System requires in order to process a case report. This implementation guide uses:

> **SHALL NOT** contain `[0..0]` **@nullFlavor**

to indicate `@nullFlavor` is not allowed for these elements.

There is a small set of data elements for which a `@nullFlavor` is not allowed. If this information is missing from the eICR, the PHA system cannot accurately process the case report. These data elements are (along with template conformance identifier):

- Date of the Report 3284-141)
- Facility Type 3284-14)
- Visit Date/Time 3284-5)
- Diagnoses Encounter 1198-9058)

6 EICR DATA REQUIREMENTS

6.1 CSTE Identified Data Requirements

The table below contains a set of data element requirements proposed by the CSTE and used to map data for this standard. The following sections contain reference tables and graphics of the data model used in this document.

Table 9: CSTE Data Elements

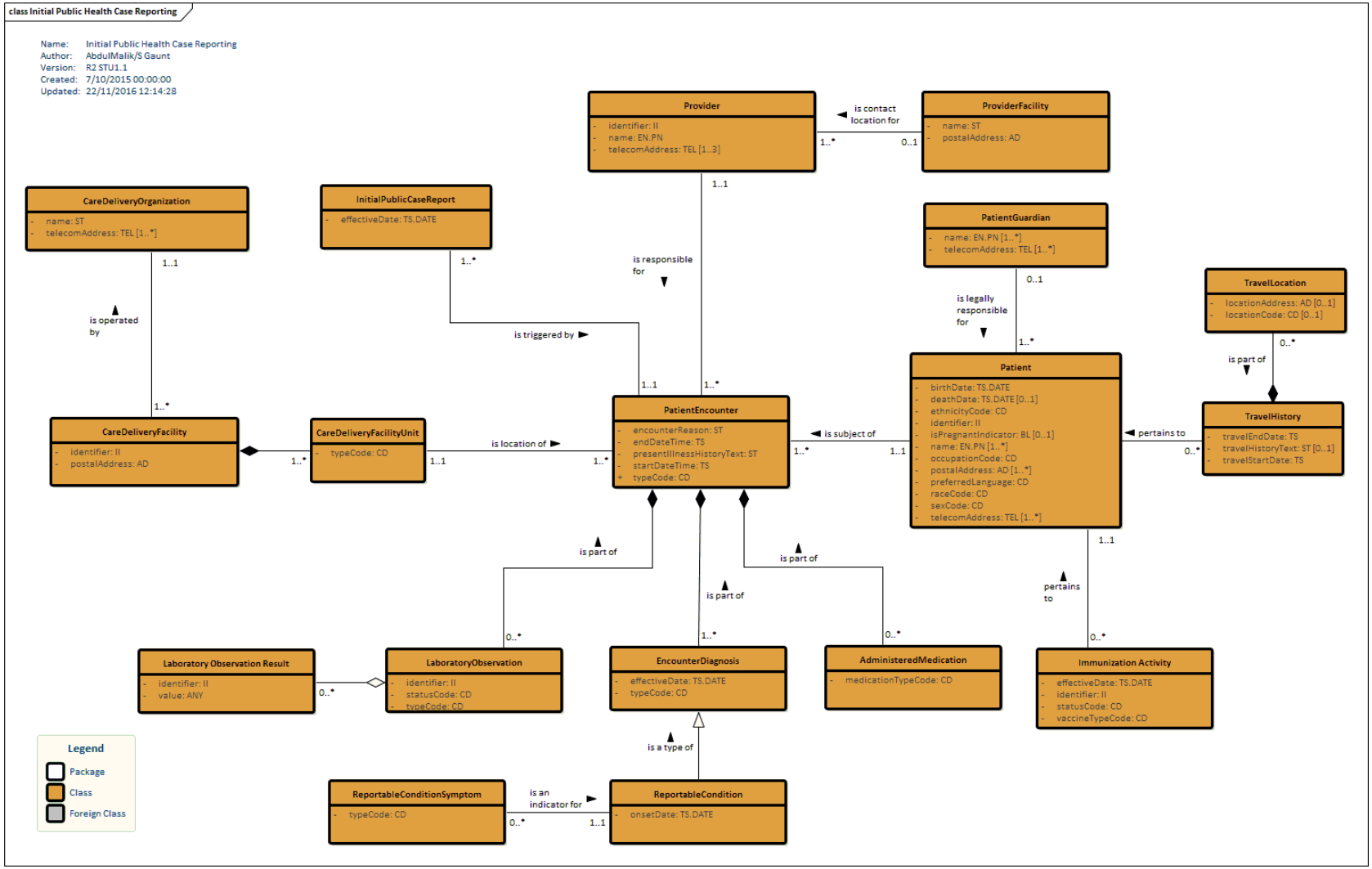
CSTE ELEMENT NAME	CSTE DESCRIPTION	RATIONALE / JUSTIFICATION
Date of the Report	The date on which the reporting party (e.g., physician, nurse practitioner, physician assistant, etc.), completes collection of minimum data for the eICR	Used to assess timelines of eICR data provisioning, and other quality assurance tasks
Report Submission Date/Time	The date and time at which the EHR system sends the eICR data to the jurisdictional public health agency or designee	Used to ensure timeliness of report and to identify time lags between date of the report and when the EHR sends the report
Sending Application	The name of the sending application	Used to ensure quality and integrity of eICR data
Provider ID	Identification code for the care provider (e.g., NPI)	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Provider Name	The first and last name of the healthcare provider	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Provider Phone	The provider's phone number with area code	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Provider Fax	The provider's fax number with area code	Necessary to obtain additional info during case follow-up phase or to submit supplemental information
Provider Email	The provider's email address	If secure email is available; used for sharing secure links to health data if allowed by state regulations
Provider Facility/Office Name	The provider facility's full name, not necessarily where care was provided to patient	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Provider Address	The geographical location or mailing address of the provider's office or facility. Address must include street address, office or suite number (if applicable), city or town, state, and zip code	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.

CSTE ELEMENT NAME	CSTE DESCRIPTION	RATIONALE / JUSTIFICATION
Facility ID Number	Identification code for the facility (e.g., Facility NPI)	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Facility Name	The facility's name	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Facility Type	The type of facility where patient received or is receiving healthcare for the reportable condition (e.g., hospital, ambulatory, urgent care, etc.)	Used to determine the type of care setting in which patient is receiving care for the reportable condition
Facility Phone	The facility's phone number with area code	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Facility Address	The mailing address for the facility where patient received or is receiving healthcare for the reportable condition. Must include street address, city/town, county, state, and zip code	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Patient ID Number	Patient social security number, medical record number, or other identifying value as required or allowed under jurisdictional laws governing health data exchange	Identification and contact; jurisdictions may select which they can receive based on laws governing public health data exchange
Patient Name	All names for the patient, including legal names and aliases. Must include the name type (i.e., legal or alias), first name, middle name, and last name	Identification and contact
Parent/Guardian Name	All names for the patient's parent or guardian, including legal names and aliases (if patient age is < 18 years). Must include name type (i.e., legal or alias), first name, middle name, and last name	For appropriate contact with minors
Patient or Parent/Guardian Phone	All phone numbers and phone number types for the patient or parent/guardian	Contact Patient
Patient or Parent/Guardian Email	The email address for the patient or the patient's parent/guardian.	Contact Patient
Street Address	All addresses for the patient, including current and residential addresses. Must include street address, apartment or suite number, city or town, county, state, zip code, and country	Case Assignment, analysis and visualization, matching
Birth Date	The patient's date of birth	Appropriate identification, appropriate identification of minors, risk; Necessary to determine patient age; matching electronic laboratory reports (ELR)
Patient Sex	The patient's biological sex (not gender)	Demographic reporting
Race	The patient's race	Demographic reporting
Ethnicity	The patient's ethnicity	Demographic reporting
Preferred Language	The patient's preferred language	Communication with Patient

CSTE ELEMENT NAME	CSTE DESCRIPTION	RATIONALE / JUSTIFICATION
Occupation	The patient's occupation	Identification of potential risk, transmission risk
Pregnant	The patient's pregnancy status	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Visit Date/Time	Date and time of the provider's most recent encounter with the patient regarding the reportable condition	Defines when the individual may have been ill; a point in time to which can link other potential cases of reportable event; necessary to ensure follow-up within key time frames/helps triage priority follow-up and ensure control measures are implemented in a timely way
Admission Date/Time	Date and time when the patient was admitted to the treatment facility; e.g., hospital	Key for epidemiologic investigation - important to know if hospitalized for severity of condition and to triage priority follow-up
History of Present Illness	Physician's narrative of the history of the reportable event. Information about possible contacts and/or exposures may be captured here.	Indicator of reportable condition - most important descriptor of condition/ epidemiologic information - supports epidemiologic investigation; epidemiologic relevant information
Reason for Visit	Provider's interpretation for the patient's visit for the reportable event	Indicator of reportable condition - most important descriptor of condition/ epidemiologic information - supports epidemiologic investigation
Date of Onset	The date of symptoms for the reportable event	Helps determine possible exposure and illness- calculate incubation period
Symptoms (list)	List of patient symptoms (structured) for the reportable event	If clinical symptoms signify a case of PH importance - confirm the need for PH follow up
Laboratory Order Code	Ordered tests for the patient during the encounter	Some lab test orders are reportable for suspected cases
Placer Order Number	Identifier for the laboratory order from the encounter	Potential value to linking electronic laboratory reports (ELR) to eICR
Diagnoses	The healthcare provider's diagnoses of the patient's health condition (all)	Would include something that is potentially reportable
Date of Diagnosis	The date of provider diagnosis	Knowing when patient is diagnosed; integral to epidemiological investigation
Medications Administered (list)	List of medications administered for the reportable event	To find treatments that were prescribed; prophylaxis; knowing if the patient has already been treated, lower on the list for PH (priority)
Death Date	The patient's date of death	Patient follow-up and epidemiological purposes
Patient Class	Whether patient is outpatient, inpatient, emergency, urgent care	
Travel History	The patient's travel history	Risk, potential severity of action, timeliness of action (e.g. is travel history relevant); Prioritization and triaging

6.2 eICR Data Model

Figure 25: The eICR Data Model documents the important data that support clinical care and public health for an electronic initial public health case report



6.3 Mapping of CSTE Identified Data Elements to eICR Data Model

The following table maps data elements identified by the CSTE task force to the eICR Data Model classes and attributes.

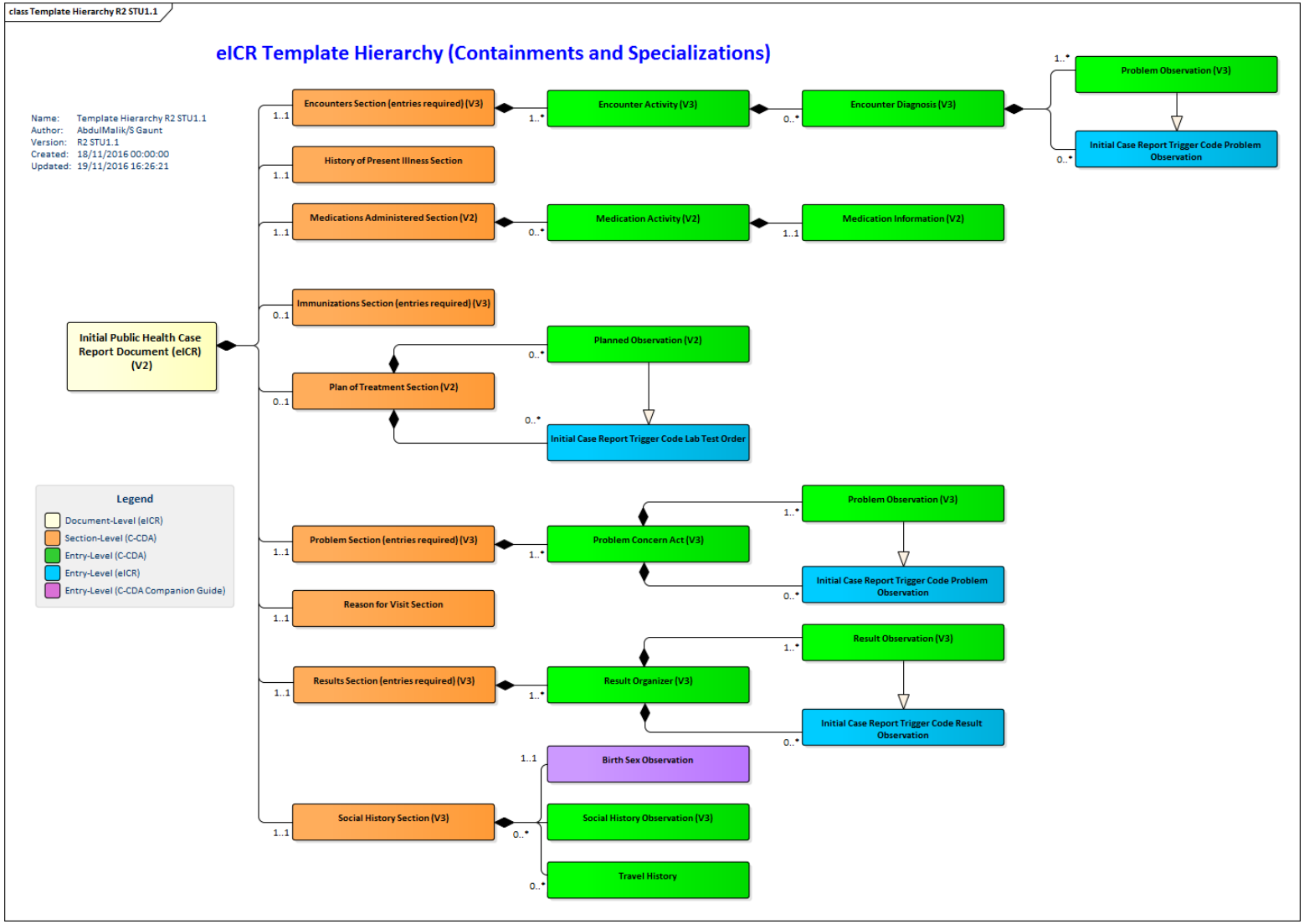
Table 10: Mapping of Data Elements to Data Model

Element Name	Class Name	Class Attribute Name
Date of the Report	IntialPublicHealthCaseReport	effectiveDate
Provider ID	Provider	identifier
Provider Name	Provider	name
Provider Phone	Provider	telecomAddress
Provider Fax	Provider	telecomAddress
Provider Email	Provider	telecomAddress
Provider Facility/Office Name	ProviderFacility	Name
Provider Address	ProviderFacility	postalAddress
Facility ID Number	CareDeliveryFacility	Identifier
Facility Name	CareDeliveryOrganization	Name
Facility Type	CareDeliveryFacilityUnit	typeCode
Facility Phone	CareDeliveryOrganization	telecomAddress
Facility Address	CareDeliveryFacility	postalAddress
Facility Fax	CareDeliveryOrganization	telecomAddress
Patient ID Number	Patient	Identifier
Patient Name	Patient	Name
Parent/Guardian Name	PatientGuardian	Name
Patient Phone	Patient	telecomAddress
Patient Email	Patient	telecomAddress
Parent/Guardian Phone	PatientGuardian	telecomAddress
Parent/Guardian Email	PatientGuardian	telecomAddress
Street Address	Patient	postalAddress
Birth Date	Patient	birthDate
Patient Sex	Patient	sexCode
Race	Patient	raceCode
Ethnicity	Patient	ethnicityCode
Preferred Language	Patient	preferredLanguage
Occupation	Patient	occupationCode
Pregnant	Patient	isPregnantIndicator
Visit Date/Time	PatientEncounter	startDateTime
Admission Date/Time	PatientEncounter	startDateTime
Hospital Unit	CareDeliveryFacilityUnit	typeCode
Discharge Date	PatientEncounter	endDateTime
History of Present Illness	PatientEncounter	presentIllnessHistoryText
Reason for Visit	PatientEncounter	EncounterReason
Date of Onset	ReportableCondition	onsetDate
Symptoms (list)	ReportableConditionSymptom	typeCode
Laboratory Order Code	LaboratoryObservation	typeCode
Filler Order Number	LaboratoryObservation	identifier

Element Name	Class Name	Class Attribute Name
Laboratory Results	LaboratoryObservationResult	value
Diagnoses	EncounterDiagnosis	typeCode
Date of Diagnosis	EncounterDiagnosis	effectiveDate
Medications Administered (list)	AdministeredMedication	medicationTypeCode
Immunization Status	ImmunizationActivity	vaccineTypeCode
Death Date	Patient	deathDate
Patient Class	PatientEncounter	typeCode
Travel History Start Date	TravelHistory	travelHistoryStartDate
Travel History End Date	TravelHistory	travelHistoryEndDate
Text Description of Travel	TravelHistory	travelHistoryText
Travel Location Code	TravelLocation	locationCode
Travel Location Address	TravelLocation	locationAddress

6.4 eICR CDA Template Hierarchy

The following diagram shows the hierarchy of CDA templates used in the eICR. Figure 26: eICR Template Hierarchy



6.5 Mapping of CSTE Identified Data Elements to CDA R2 Templates

The following table maps data elements identified by the CSTE task force to the conformance identifiers used in Volume 2 of the Implementation Guide.

Figure 27: eICR Template Hierarchy

Data Element	CDA R2 Template	CONF #	Note
Date of the Report	US Realm Header (V3)	1198-5256	
Provider ID	eICR Initial Public Health Case Report Document (V2)	3284-8	This data element can repeat.
Provider Name	eICR Initial Public Health Case Report Document (V2)	3284-25	
Provider Phone	eICR Initial Public Health Case Report Document (V2)	3284-24	URL.scheme = 'tel:'. This data element can repeat.
Provider Fax	eICR Initial Public Health Case Report Document (V2)	3284-24	URL.scheme = 'tel:'. This data element can repeat.
Provider Email	eICR Initial Public Health Case Report Document (V2)	3284-24	URL.scheme = 'mailto:'. This data element can repeat.
Provider Facility/Office Name	eICR Initial Public Health Case Report Document (V2)	3284-26	
Provider Address	eICR Initial Public Health Case Report Document (V2)	3284-27	
Facility ID Number	eICR Initial Public Health Case Report Document (V2)	3284-13	
Facility Name	eICR Initial Public Health Case Report Document (V2)	3284-33	
Facility Type	eICR Initial Public Health Case Report Document (V2)	3284-14	
Facility Phone	eICR Initial Public Health Case Report Document (V2)	3284-34	URL.scheme = 'tel:'. This data element can repeat.
Facility FAX	eICR Initial Public Health Case Report Document (V2)	3284-34	URL.scheme = 'tel:'. This data element can repeat.
Facility Address	eICR Initial Public Health Case Report Document (V2)	3284-32	This data element can repeat.
Patient Class	US Realm Header (V3)	3284-4	
Patient ID Number	US Realm Header (V3)	1198-5268	This data element can repeat.
Patient Name	US Realm Header (V3)	1198-5284	This data element can repeat.
Patient Phone	US Realm Header (V3)	1198-5280	URL.scheme = 'tel:'. This data element can repeat.
Patient Email	US Realm Header (V3)	1198-5280	URL.scheme = 'mailto:'. This data element can repeat.
Parent/ Guardian Name	US Realm Header (V3)	1198-5386	This data element can repeat.
Parent/ Guardian Phone	US Realm Header (V3)	1198-5382	URL.scheme = 'tel:'. This data element can repeat.
Parent/ Guardian Email	US Realm Header (V3)	1198-5382	URL.scheme = 'mailto:'. This data element can repeat.
Street Address	US Realm Header (V3)	1198-5271	This data element can repeat. Use <addr><county/><addr> to record county.
Birth Date	US Realm Header (V3)	1198-5298	
Patient Sex	Birth Sex Observation	3250-32947	This not patient gender in the US Realm Header.

Data Element	CDA R2 Template	CONF #	Note
Race	US Realm Header (V3)	1198-5322 1198-7263	This data element can repeat.
Ethnicity	US Realm Header (V3)	1198-5323 1198-32901	This data element can repeat.
Preferred Language	US Realm Header (V3)	1198-5407	This data element can repeat.
Occupation	Social History Observation (V3)	1198-8559	Observation.code = SCTID: 14679004 This data element can repeat.
Pregnant	Problem Observation (V3)	1198-9058	During the DSTU period, the use of the Problems Observation template to indicate pregnancy is being evaluated. The recommended SNOMED value codes are '60001007' Not pregnant (finding), and '77386006' Patient currently pregnant (finding).
Hospital Unit	eICR Initial Public Health Case Report Document (V2)	3284-14	
Visit Date/Time	eICR Initial Public Health Case Report Document (V2)	3284-20	For outpatient encounters
Admission Date/Time	eICR Initial Public Health Case Report Document (V2)	3284-20	For Inpatient encounters
Discharge Date/Time	eICR Initial Public Health Case Report Document (V2)	3284-21	For Inpatient encounters
History of Present Illness	History of Present Illness Section	81-7851	This data element can repeat within the text element of this narrative only template.
Reason for Visit	Reason for Visit Section	81-7839	This data element can repeat within the text element of this narrative only template.
Date of Onset	Problem Observation (V3)	1198-15603	This data element can repeat.
Symptoms (list)	Problem Observation (V3)	1198-9058	This data element can repeat.
Lab Order Code	Planned Observation (V2)	1198-30453	This data element can repeat. Ordered lab test name.
Lab Order Code	Result Observation (V3)	1198-7133	This data element can repeat. Resulted lab test name.
Lab Order Code (Trigger)	Initial Case Report Trigger Code Lab Test Order		Ordered lab test name. This data element can repeat.
Lab Order Code (Trigger)	Initial Case Report Trigger Code Result Observation	3284-271	Resulted lab test name. This data element can repeat.
Laboratory Results	Result Observation (V3)	1198-7143	This data element can repeat.
Laboratory Result (Trigger)	Initial Case Report Trigger Code Result Observation	3284-273	This data element can repeat.
Filler Order Number	Result Organizer (V3) Result Observation (V3)	1198-7127 1198-7137	This data element can repeat.
Diagnoses	Problem Observation (V3)	1198-9058	Observation.code = LOINC: 29308-4. This data element can repeat.
Diagnosis (Trigger)	Initial Case Report Trigger Code Problem Observation	3284-106	This data element can repeat.

Data Element	CDA R2 Template	CONF #	Note
Date of Diagnosis	Problem Observation (V3)	1198-9050	This data element can repeat.
Medications Administered (list)	Medication Information (V2)	1098-7412	This data element can repeat.
Death Date	eICR Initial Public Health Case Report Document (V2)	3284-106	
Immunization Status	Immunizations Section (entries required) (V3)	3284-149	
Travel History Dates	Travel History	3284-295	
Travel History Location - Free Text	Travel History	3284-269	
Travel History Location - Coded	Travel History	3284-263	
Travel History Location - Address	Travel History	3284-264	

APPENDIX A — ACRONYMS AND ABBREVIATIONS

APHL	Association of Public Health Laboratories
ASTHO	Association of State and Territorial Health Officials
C-CDA R2.1	Consolidated CDA Templates for Clinical Notes, DSTU 2.1
C-CDA R2.1 CG	C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 1
CCD	Continuity of Care Document
CDA R2	Clinical Document Architecture (Release 2)
CDC	Centers for Disease Control and Prevention
CPT	Current Procedural Terminology
CSTE	Council of State and Territorial Epidemiologists
DAM	Domain Analysis Model
DICOM	Digital Imaging and Communications in Medicine
DRIV	is derived from
DSTU	Draft Standard for Trial Use
EHR	electronic health record
eCR	electronic case reporting
eICR	electronic initial case report
eICR IG	Public Health Case Report, R2, Standard for Trial Use Release 1.1
EMR	electronic medical record
EVN	event
GOL	goal
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HTML	Hypertext Markup Language
ICD	International Classification of Diseases
IG	implementation guide
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standard Development Organisation
RFC	Request for Comments
ITI	information technology infrastructure
LOINC	Logical Observation Identifiers Names and Codes
MHTML	MIME HTML
MIME	Multipurpose Internet Mail Extensions

NA	not applicable
NI	no information
NPI	National Provider Identifier
NUBC	National Uniform Billing Committee
NUCC	National Uniform Claim Committee
OID	object identifier
ONC	Office of National Coordinator
OTH	not an element in the value domain
PCDATA	Parsed Character Data
PHER	HL7 Public Health and Emergency Response Work Group
PDF	Portable Document Format
RCTC	Reportable Condition Trigger Code
RFC	request for comment
RIM	Reference Information Model
RMIM	Refined Message Information Model
RQO	request
S&I	Standards and Interoperability
sdtc	Structured Documents Technical Committee (namespace identifier)
SDWG	HL7 Structured Documents Working Group
SNOMED CT	Systemized Nomenclature for Medicine – Clinical Terms
SSN	Social Security Number
STU	Standard for Trial Use
UCUM	Unified Code for Units of Measure
UDI	Unique Device Identification
UML	Unified Modeling Language
UNK	unknown
URL	uniform resource locator
URN	uniform resource name
UUID	universally unique identifier
XML	eXtensible Markup language
XPath	XML Path Language

APPENDIX B — HIGH LEVEL CHANGE LOG

The following sections give a high-level overview of the changes between this current STU update release of the *Public Health Case Report, Release 1, STU Release 1.1 - US Realm* and the previous STU release *Public Health Case Report, Release 1, STU Release 1 - US Realm.* For a detailed template change log, see Section 8, Changes from Previous Version, in Volume 2 of this Implementation Guide.

Volume 1 Summary of Changes

- Typo corrections, non-substantive wording changes were made throughout the document but these changes will not be detailed.
- New chapters/sections/appendices (only the top heading-level of the addition is noted):
  - **1.3** Organization of the Guide
  - **1.6** Current Project
  - **3** CDA R2 Background
  - **5.2** Stand-Alone Templates
  - **5.4** Trigger Code Templates
  - **Appendix A** — Acronyms and Abbreviations
  - **Appendix B** — High Level Change Log
  - **Appendix B — Error! Not a valid bookmark self-reference.**
- Updated chapters/sections:
  - **4** Using This Implementation Guide
    - replaced "Conventions used in this implementation guide" section
  - **4.1** Conformance Conventions Used in This Guide
  - **4.1.1** Templates and Conformance Statements
  - **4.2** XML Conventions Used in This Guide
    - Split chapter "Data Requirements and IG Template Specifications Organization" into the following two chapters:
  - **5** eICR IG Specific Conformance Guidance
  - **6** eICR Data Requirements
    - Updated tables and diagrams to reflect new data elements and added sections (see above)

Volume 2 Summary of Changes

- Document-Level Templates
  - No new document-level templates were added.
  - Initial Public Health Case Report Document (eICR) was versioned to V2:
    - Added containment for C-CDA R2.1: Plan of Treatment (V2) Section

        - Added containment for Birth Sex Observation
        - Added @sdtc:deceasedInd
        - Updated constraint for @sdtc:deceasedTime
        - Added guidance for using county in an address
        - Updated examples
- Section-Level Templates
    - One new section-level template was added:
        - C-CDA R2.1: Plan of Treatment (V2) Section
- Entry-Level Templates
    - Six new entry-level templates were added:
        - C-CDA R2.1 Companion Guide: Birth Sex Observation
        - C-CDA R2.1 Based: Initial Case Report Trigger Code Lab Test Order
        - C-CDA R2.1 Based: Initial Case Report Trigger Code Problem Observation
        - C-CDA R2.1 Based: Initial Case Report Trigger Code Result Observation
        - C-CDA R2.1 Based: Initial Case Report Manual Initiation Reason Observation
        - Travel History
- Value Sets
    - Seven new value sets were added:
        - Initial Case Report Trigger Code Result Status
        - ONC Administrative Sex
        - Reportable Conditions Trigger Code Value set
        - Trigger code for condition name (RCTC subset)
        - Trigger code for laboratory test names (RCTC subset)
        - Trigger code for laboratory test orders (RCTC subset)
        - Trigger code for organism or substance (RCTC subset)

APPENDIX C — EXTENSIONS TO CDA R2

Where there is a need to communicate information for which there is no suitable representation in CDA R2, extensions to CDA R2 have been developed. These extensions are described in the context of the section where they are used. This section serves to summarize the extensions and provide implementation guidance. For a full list of approved CDA extensions, see: CDA_R2_Extensions.

Extensions used in this guide include:

Extension	Definition/Usage
sdtc:raceCode	The raceCode extension allows for multiple races to be reported for the recordTarget. • recordTarget/patientRole/patient • Cardinality: [0..*]
sdtc:ethnicGroupCode	The ethnicGroupCode extension allows for additional ethnicity groups to be reported for the recordTarget. • recordTarget/patientRole/patient • Cardinality: [0..*]
sdtc:deceasedInd	The deceasedInd extension (= "true" or "false") is used to record that the recordTarget is deceased. • recordTarget/patientRole/patient • Cardinality: [0..1]
sdtc:deceasedTime	The deceasedTime extension is used to record the date and time of death of the recordTarget. • recordTarget/patientRole/patient • Cardinality: [0..1]
sdtc:dischargeDispositionCode	The dischargeDispositionCode extension allows the provider to record a discharge disposition in an encounter activity. • encounter • Cardinality: [0..1]
sdtc:signatureText	The signatureText extension provides a location in CDA for a textual or multimedia depiction of the signature by which the participant endorses and accepts responsibility for his or her participation in the Act as specified in the Participation.typeCode. Details of what goes in the field are described in the HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1. • authenticator • legalAuthenticator • Cardinality: [0..1]

Extension	Definition/Usage
sdtc:valueSet	The valueSet extension allows the implementer to reference a particular value set from which a code was drawn. • CD data type • Cardinality: [0..1]
sdtc:valueSetVersion	The valueSetVersion extension allows the implementer to reference a specific version of a value set. • CD data type • Cardinality: [0..1]

To resolve issues that need to be addressed by extension, the developers of this guide chose to approach extensions as follows:

- An extension is a collection of element or attribute declarations and rules for their application to the CDA Release 2.0.
- All extensions are optional. An extension may be used, but need not be under this guide.
- A single namespace for all extension elements or attributes that may be used by this guide will be defined.
- The namespace for extensions created by the HL7 Structured Documents Working Group (formerly Structured Documents Technical Committee) shall be urn:hl7-org:sdtc.
- This namespace shall be used as the namespace for any extension elements or attributes that are defined by this implementation guide.
- Each extension element shall use the same HL7 vocabularies and data types used by CDA Release 2.0.
- Each extension element shall use the same conventions for order and naming as is used by the current HL7 tooling.
- An extension element shall appear in the XML where the expected RIM element of the same name would have appeared.

