



**HL7 CDA® R2 Implementation Guide:**  
**Public Health Case Report – the Electronic Initial Case**  
**Report (eICR) Edition 4 – US Realm**

January 2026

**HL7 STU Ballot**

**Volume 1 – Introductory Material**

**Sponsored by:**  
**Public Health Work Group**

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## Structure of This Guide

Two volumes comprise this *HL7 CDA® R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR) Release 1, STU Release 4.0.0 - US Realm*. 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.

## Acknowledgements

This guide was produced and developed through a collaborative effort of the Centers for Disease Control and Prevention (CDC), Council of State and Territorial Epidemiologist (CSTE), the Association of State and Territorial Health Officials (ASTHO), the Association of Public Health Laboratories (APHL), public health surveillance practitioners, electronic health record (EHR) vendors, and the Health Level Seven (HL7) Public Health (PH) Work Group for an electronic initial case report (eICR). A list of data elements for eICRs was developed by the CSTE Electronic Initial Case Report Task Force in collaboration with the CDC. Pregnancy status data for public health reporting were identified by a task force from the Department of Health and Human Services, Office of the National Coordinator for Health IT (ONC). CDC provided some funding to our partner organizations to support these activities. The project team that participated in the development of this implementation guide is:

- Laura A. Conn, Director, Health Information Strategy Activity, CSELS, CDC and Member, CSTE eICR Task Force
- Erin Holt Coyne, Tennessee Department of Health, and Co-chair, HL7 PH Work Group, and Member, CSTE eICR Task Force
- Kailah Davis, APHL
- Sarah Gaunt, Senior Information Analyst, Lantana Consulting Group
- Rick Geimer, Chief Innovation Officer, Lantana Consulting Group
- Joel Hartsell, APHL
- John W. Loonsk, Johns Hopkins University Center for Population Health IT, consultant to APHL, and Executive Sponsor, Public Health Case Report Project, PH Work Group
- Sean McIlvenna, Information Technology (IT) Manager and Senior Software Architect, Lantana Consulting Group
- Wendy L. Wise, Senior Project Manager, Lantana Consulting Group

This and predecessor documents were reviewed by many national and state public health organizations, standards development organizations and vendors. The authors and editors would like to express gratitude to these reviewers for their thoughtful comments and support during development of this guide. In addition, special thanks need to be expressed to the following organizations who contributed to this document:

- Association of Public Health Laboratories (APHL)
- Association of State and Territorial Health Officials (ASTHO)
- Centers for Disease Control and Prevention Centers (CDC)/Institutes/Offices:
  - Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
  - Office of Infectious Diseases
  - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
  - National Center for Health Statistics (NCHS)
  - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)
  - National Institute for Occupational Safety and Health (NIOSH)
- Council of State and Territorial Epidemiologists (CSTE)
- Public Health Informatics Institute (PHII)

Others who contributed to this, and predecessor, documents include:

- Chad Albent, InterSystems
- Marla Albitz, Wolters Kluwer
- Noam Artz, HLN Consulting

- Rita Altamore, Washington Department of Health
- Nancy Barrett, Connecticut Department of Public Health
- Dan Chaput, Office of the National Coordinator for Health IT, HHS
- Michael Clifton, Epic
- Glenn Copeland, Michigan Department of Health and Human Services
- James Daniel, HHS
- Virginia Dato, University of Pittsburgh School of Medicine
- Sherri Davidson, Alabama Department of Health
- Dave deRoode, Lantana Consulting Group
- George Dixon, AllScripts
- Jean Duteau, Duteau Design, Inc.
- John Eichwald, CDC
- Eric Haas, Health eData
- Janet Hamilton, CSTE
- John Hatem, Oracle
- Richard Hornaday, AllScripts
- Janet Hui, HLN Consulting
- Ray Humphreys, Altarum Institute
- Mario Hyland, AEGIS
- Jim Jellison, PHII
- Ramya Kommareddi, Altarum Institute
- Austin Kreisler, Leidos
- Nell Lapras, Epic
- Eric Larson, Northrup Grumman
- Meredith Lichtenstein, CSTE
- Julie Lipstein, Inductive Health
- Claire Loe, PHII
- Genevieve Luensman, CDC
- Joginder Madra, Madra Consulting
- Tonya Martin, CDC
- Ulrike Merrick, APHL
- Maiko Minami, HLN Consulting
- Sunanda McGarvey, Northrup Grumman
- Craig Newman, Altarum Institute
- M'Lynda Owens, Cognosante
- Laura Rappleye, Altarum Institute
- Lori Reed-Forquet, eHealthSign
- Marcus Rennick, ASTHO
- Bryn Rhodes, Dynamic Content Group
- John Roberts, Tennessee Department of Public Health
- Mitra Rocca, Food and Drug Administration
- Mark Roche, Office of the National Coordinator for Health IT, HHS
- Dan Rutz, Epic
- Rob Savage, Rob Savage, LLC
- K.P. Sethi, Lantana Consulting
- AbdulMalik Shakir, Hi3 Solutions and Shakir Consulting
- Catherine Staes, University of Utah
- John Stamm, Epic
- Walter Suarez, Kaiser Permanente

- Jenni Syed, Cerner
- Mead Walker, Mead Walker Consulting
- Kathy Walsh, LabCorp
- Michelle Williamson, CDC
- Danny Wise, AllScripts
- Mike Yaskanin, Altarum Institute
- Daniel Zhang, Epic

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# 1 INTRODUCTION

## Notes to Ballot Readers

*This section will be removed in the published version of the IG.*

### Items for Voting

This ballot contains two volumes. Below are descriptions of items that may be voted on in each volume.

#### Volume 1:

- The body of the document up until the appendices **MAY be voted on.**

#### Volume 2:

- Templates that are part of this implementation guide new or revised are signified by the wording “part of Public Health Case Report” below the template name. **These MAY be voted on.**
- Templates that have been brought in unchanged from another implementation guide are signified by the wording “part of <name of IG>” (where <name of IG> is NOT "Public Health Case Report") below the template name. **These MAY NOT be voted on.**

### Commenter Feedback Requests

1. **eICR IG Format:** We are evaluating a new approach for the Electronic Initial Case Report (eICR) CDA Implementation Guide (IG). Today, the eICR CDA IG is published as a single, comprehensive guide containing all templates needed to construct an eICR CDA document. We are considering shifting to a model where the IG includes only new or revised templates—similar to the format of the [C-CDA Companion Guide](#), which many implementers already use. The “[stand-alone](#)” templates already published in this IG are strong candidates for this type of publication. This change would result in a smaller, more focused, and easier-to-navigate publication. Schematron and sample files would continue to be included. We welcome feedback on this proposed approach.
2. **Specimen Information:** the C-CDA Companion Guide (C-CDA CG) contains the [Results Observation](#) and [Results Organizer](#) templates that implement the US Core Data for Interoperability (USCDI) Specimen requirements. Currently eICR uses the Specimen collection templates from the C-CDA R2.1 Supplemental Templates for Infectious Diseases (ID). Going forward should eICR:
  - a) Continue using only the ID templates
  - b) Use both the C-CDA CG and the ID templates
  - c) Change to using only the C-CDA CG templates
3. **Occupation & Industry:** the C-CDA Companion Guide (C-CDA CG) contains the [Basic Occupation Observation](#) and the [Basic Industry Occupation](#) profiles that implement the USCDI Occupation and Occupation Industry requirements.

Currently eICR uses the Occupational Data for Health (ODH) CDA templates. Going forward should eICR:

- a) Continue using only the ODH templates
- b) Use both the C-CDA and the ODH templates
- c) Change to using only the C-CDA templates

**4. Aborted Medications**

- a) Should aborted medications be disallowed in the eICR?

**5. Pregnancy Intent:**

- a) Should the [C-CDA Pregnancy Intention in the Next Year](#) template be included in the eICR, and, if included, what specific public health utility or use cases would it support?

**6. Vital Signs:**

- a) What vital signs are most pertinent?
- b) What guidance should be given on the relevant time period/filter for vital signs included/sent in the eICR?

## 1.1 Purpose

The purpose of this *HL7 CDA® R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR) Release 2, STU Release 4.0.0 - US Realm* (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 reportable event data 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), these reportable event data will also indirectly support notifications between PHAs and 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 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. Reportable event data from EHRs is also important to public health surveillance for critical clinical data, under-reported clinical cases, emergency management of new conditions, and for conditions for which a laboratory result is not a definitive criterion. Reportable event data from EHRs complements electronic laboratory reporting through earlier reporting and by providing clinical and demographic data that may not be included in laboratory reports.

The 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. 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 (RCTC) in the electronic Reporting and Surveillance Distribution (eRSD). The eICR will then convey initial reportable event data to public health and support 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 reportable event data 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 by a number of different transport methods. It will serve as input for reportability evaluation performed by a public health decision support system.

Out of scope for this IG, but in the companion HL7 CDA Reportability Response standard is the specification for public health to communicate back to the reporting healthcare provider / organization for each eICR that is received. The Reportability Response conveys the reportability of a condition, information on that condition in the relevant jurisdiction(s), and other supporting public health information back to clinical care personnel. It also serves as an acknowledgment of successful eICR submission or conveys error and warning information back to the reporting healthcare EHR administrator.

With the advent of the HL7 Fast Healthcare Interoperability Resources (FHIR) standard, some EHR vendors have indicated that they would prefer to implement electronic case reporting (eCR) in FHIR, while others have indicated that HL7 CDA remains the best way of getting data out of EHRs. To support these possibilities for the foreseeable future, we have also created HL7 FHIR versions of the HL7 CDA eICR, the HL7 CDA Reportability Response, and an electronic Reporting and Surveillance Distribution (eRSD) transaction that enables the electronic distribution of RCTC trigger codes and reporting guidance from public health to clinical care. The HL7 FHIR eCR standard includes FHIR versions of the eICR, the Reportability Response, and the eRSD transaction in one implementation guide and standard.

Not included as part of these standards but intended as a tool to facilitate industry adoption thereof, we are also providing data transforms that convert the CDA eICR and Reportability Response to the FHIR versions and vice versa. The HL7 FHIR eRSD Transaction can be used by EHRs that support and those that don't yet support HL7 FHIR.

## **1.2 Audience**

This implementation guide is designed to provide EHR vendors with the specifications for developing the functionality of EHRs used in hospitals and by ambulatory care providers to provide reportable event data to PHAs. This implementation guide 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 implementation guide will also be informative to health care providers, public health staff, analysts, and health information exchange organizations, among others. Users of this implementation guide must be familiar with the details of the HL7 CDA R2 document construction and the *Consolidated CDA*

*Templates for Clinical Notes, DSTU 2.1<sup>1</sup> (C-CDA R2.1) and C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 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.

**Chapter 5**—eICR implementation guide 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.

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<sup>1</sup> [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=492](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=492)

**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 implementation guide - these are listed here: [Volume 2 Summary of Changes](#).)

## 1.4 Background

State, local, and territorial laws and regulations require the transmission of reportable event data and, at times, suspected reportable event data of certain infectious and non-infectious conditions to public health agencies (PHAs) to support disease monitoring and surveillance. For the purpose of this implementation guide, related notifications from PHAs to the 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 the transmission of reportable event data from clinical care to PHAs 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 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.<sup>2</sup>

Reportable event data 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 data to enable these activities.

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<sup>2</sup> <http://www.cdc.gov/media/releases/2013/p0819-lyme-disease.html>

Previous efforts to develop standards for the exchange of reportable event 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.

Stage 3 of the CMS EHR Incentive Program (Meaningful Use) program and the subsequent Promoting Interoperability program identified electronic public health case reporting as an option for clinical reporters to meet criteria. A goal of this implementation guide is to contribute to future certification criteria to ensure that consistent, comparable case reports are received by PHAs 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 implementation guide builds on experience, specifications and lessons learned from the previous releases of the *HL7 CDA® R2 Implementation Guide : Public Health Case Reporting*; the ONC Standards and Interoperability (S&I) Framework Public Health Case Reporting Initiative (PHRI); the 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).<sup>3</sup> Most recently the Robert Wood Johnson Digital Bridge<sup>4</sup> effort has focused on electronic case reporting as well. More information on some of this work can be found here: [ecr.aimsplatform.org](http://ecr.aimsplatform.org).

## 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;
- 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 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 PHAs (Note: reports may include administrative, laboratory, pharmacy and/or other information imported from separate systems into the EHR but how these data are mapped into the eICR may vary across EHRs).

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 the HL7 CDA Reportability Response companion document, which are separately published;
- The specifications for supplemental data associated with a report of a reportable condition;

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<sup>3</sup> [www.thephcp.org](http://www.thephcp.org)

<sup>4</sup> <https://digitalbridge.us/infoex/>

- The specific methods for providers to transmit eICRs to PHAs. Some of these are described in this implementation guide for context purposes only;
- The methods for PHAs to receive and process eICRs;
- 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 PHAs 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 CDA® R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR) Edition 4 – US Realm* specification was developed and produced by the HL7 Public Health Workgroup and co-sponsored by the HL7 Structured Documents Workgroup. It aligns with USCDI V3 by updating to *C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1*, removes procedure triggering, adds susceptibility to organism matching, adds guidance on the relevant time period for retrieving various data elements from the medical record, adds the C-CDA Care Team Section, and updates guidance and narrative descriptions.

### Previous Releases

The previous releases of this project contained material to allow for inclusion of the following information in an eICR instance:

- Procedures and Procedure Triggers

The following templates have been created for optional use in a Procedures Section (entries required) (V2) contained in an Initial Public Health Case Report Document (eICR) (V4):

- Initial Case Report Trigger Code Procedure Activity Procedure
- Initial Case Report Trigger Code Procedure Activity Act
- Initial Case Report Trigger Code Procedure Activity Observation

have been created for optional use in a Procedures Section (entries required) (V2) Section contained in an Initial Public Health Case Report Document (eICR) (V4).

They indicate that the procedure code is a trigger code and further constrain the following C-CDA R2.1 templates:

- Procedure Activity Procedure (V2)
  - Procedure Activity Act (V2)
  - Procedure Activity Observation
- Planned Procedure Triggers

The following templates:

- Initial Case Report Trigger Code Planned Procedure
  - Initial Case Report Trigger Code Planned Act
  - Initial Case Report Trigger Code Planned Observation

have been created for optional use in a Plan of Treatment Section (V2) contained in an Initial Public Health Case Report Document (eICR) (V4). They indicate that the procedure code is a trigger code and further constrain the following C-CDA R2.1 templates:

- Planned Procedure (V2)
  - Planned Act (V2)
  - Planned Observation (V2)
- Disability Status
- Emergency Outbreak Information
- Exposure/Contact Information
- Purpose of Travel
- Transportation Details
- Reportability Response Information
- Admission & Discharge Diagnoses
- Past Medical History
- Review of Systems
- 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 eICRs is dependent on EHR implementers having a list of codes related to reportable diseases that can be easily matched against relevant patient record data (part of the eRSD). 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 eICR implementation guide 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 implementation of travel history in this CDA implementation guide represents a 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 birth sex
  - Patient birth sex represents the sex of the patient at birth. It is the sex that is entered on the person's birth certificate at the time of birth. This concept is not the same as patient gender (administrativeGender in the US Realm Header) nor is it same as Gender Identity.
- Flagging of a manually initiated eICR document and recording the reason for the manual initiation.
- Pregnancy status reporting information
  - The *HL7 CDA® R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Pregnancy Status*<sup>5</sup> contains pregnancy templates that have been developed for general use
  - This eICR implementation guide is using a subset of these templates needed for public health reporting based on the HHS Public Health Task Force recommendations
- Work Information Data
  - *HL7 CDA® R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Occupational Data for Health*<sup>6</sup> have been developed for general use
  - This eICR implementation guide is using a subset of these templates to convey the information required for this public health reporting use case
- Vital signs
  - Adding C-CDA R2.1 Vital Signs Section to convey vital signs information required for this public health reporting use case
- Lab test status and specimen source data
  - C-CDA R2.1 Supplemental Templates for Infectious Disease have been developed for general use
  - This eICR implementation guide is using a subset of these templates to convey the information required for this public health reporting use case
- Gender Identity

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<sup>5</sup> [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=494](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=494)

<sup>6</sup> [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=522](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=522)

- The Gender Identity Observation template from the *HL7 CDA® R2 Implementation Guide: National Health Care Surveys (NHCS)*<sup>7</sup> has been added to convey the patient's gender identity, defined as "One's basic sense of being male, female, or other gender (for example, transgender or gender queer). Gender identity can be congruent or incongruent with one's sex assigned at birth based on the appearance of external genitalia." (Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the Lesbian, Gay, Bisexual, and Transgender (LGBT) Community—A Field Guide, The Joint Commission (2011).) This observation is not appropriate for recording patient gender (administrativeGender) or birth sex.
- Therapeutic Response to Medication
  - The Therapeutic Medication Response Observation template has been created to represent a therapeutic response (as opposed to an undesired reaction) to the administration of a medication.
- Medication Trigger
  - The Initial Case Report Trigger Code Medication Information template has been created for optional use in a Medication Activity (V2) or a Planned Medication Activity (V2) contained in an Initial Public Health Case Report Document (eICR) (V3). It indicates that the medication code is a trigger code, and it further constrains the C-CDA R2.1 Medication Information (V2) template.
- Immunization Trigger
  - The Initial Case Report Trigger Code Immunization Medication Information template has been created for optional use in an Immunization Activity (V3) or a Planned Immunization Activity contained in an Initial Public Health Case Report Document (eICR) (V3). It indicates that the vaccine code is a trigger code, and it further constrains the C-CDA R2.1 Immunization Medication Information (V2) template.

## 1.7 Errata or Enhancements

Comments regarding errata or enhancements may be entered as Jira issues here:

<https://jira.hl7.org/projects/CDA/issues>.

## 1.8 Stakeholders

**Figure 1: The key stakeholder groups interested in eICR Use Case**

Stakeholders	Description
Electronic Health Record (EHR) / Electronic Medical Record (EMR)	<p>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.</p> <p>Source:  <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2518657/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2518657/</a>.            For purposes of this IG, EHR can also be interpreted to refer</p>

<sup>7</sup> [https://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=385](https://www.hl7.org/implement/standards/product_brief.cfm?product_id=385)

Stakeholders	Description
	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.
Intermediary	An organization that is in the information flow between a healthcare organization and a PHA regarding case reporting. An intermediary may be acting on behalf of either the healthcare organization as a business associate or public health as an authorized agent. Examples include a Health Information Exchange (HIE) organization, a clinical trust and exchange network, or a shared infrastructure and routing platform.
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.
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 standards development organization.

## 1.9 U.S. Core Data for Interoperability (USCDI) Alignment

Alignment with USCDI is important to get data as readily as possible from clinical care and minimize provider burden. The CDA eICR implementation guide is built extensively on published HL7 C-CDA R2.1 and HL7 C-CDA Companion Guide 4.1 templates, which are aligned with USCDI V3. There are some eICR data, critical to public health activities that are in the eICR but not in the USCDI at this time. As well, some USCDI data are not legally authorized for delivery to PHAs in the context of case reporting, but every effort will be made in an ongoing way to minimize variations from the USCDI. The FHIR version of the eICR transaction, maps to US Core profiles<sup>8</sup> on which the USCDI is based.

We will continue to align with USCDI as it progresses. eCR data elements for potential inclusion in future versions of USCDI have been submitted to USCDI using the USCDI ONC New Data Element and Class (ONDEC) Submission System.

The following table illustrates a high-level mapping from USCDI v3 to eICR.

**Table 1: High-Level Mapping from USCDI v3 to eICR**

USCDI V3 Data Class/Element	eICR Data Class/Element
Care Team Members	Provider
Immunizations	Immunization Status
Medications	Medications Administered (list)
Laboratory	Laboratory
Patient Demographics: Address	Patient Address
Patient Demographics: Birth Sex	Patient Birth Sex
Patient Demographics: Date of Birth	Birth Date
Patient Demographics: Ethnicity	Ethnicity
Patient Demographics: First Name Patient Demographics: Last Name Patient Demographics: Middle Name Patient Demographics: Suffix	Patient Name
Patient Demographics: Phone Number	Patient Phone
Patient Demographics: Preferred Language	Preferred Language
Patient Demographics: Race	Race
Patient Demographics: Tribal Affiliation	Tribal Affiliation
Pregnancy Status	Pregnancy Status
Problems	Diagnosis/Diagnosis (Trigger)
Procedures	Procedure/Procedure
Vital Signs	Vital Signs

<sup>8</sup> <https://www.hl7.org/fhir/us/core/>

USCDI V3 Data Class/Element	eICR Data Class/Element
Encounter	Visit
Disability Status	Disability Status

## 1.10 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 reportable event exchange between EHRs and PHAs. 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 and other reporting guidance, e.g., from public health to a provider's EHR system. This specification exists in the HL7 FHIR eCR standard's eRSD transaction.
2. The CSTE and the CDC have developed a list of reportable condition trigger codes (RCTCs) that EHR vendors can implement to identify relevant clinical diagnoses, laboratory results and some orders. The trigger code list and other reporting guidance is offered through the H7 FHIR eRSD transaction (for use by FHIR and non-FHIR EHRs) and can be found here ([ersd.aimsplatform.org](https://ersd.aimsplatform.org)).
3. The HL7 CDA Reportability Response companion standard - a specification for return communication from public health to clinical care, specific to the patient and eICR in question, and potentially including information about that condition in that community. In addition to the specifics to identify the related initial case report, the Reportability Response contains information such as whether the condition is definitively reportable to the PHA in that jurisdiction(s), if there are additional data needed to definitively determine reportability, information about outbreaks or related trends, information about who to contact in the PHA if there are issues to work through via other means, links to the full reporting requirements in that jurisdiction, and acknowledgment information including any errors or warnings needed by EHR System Administrators. It also may include links to forms for the input of supplemental data desired for that condition and potentially other information as necessary for public health activities.
4. While partly handled in the HL7 CDA Reportability Response, other 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 public health alerts viewable by clinical staff from within an EHR, as well as be computable and query-able. 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 IHE RFD or ONC Structured Data Capture (SDC) 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. The HL7 CDA eICR and Reportability Response are also manifest in the HL7 FHIR eCR standard<sup>[1]</sup>. Also, in the HL7 FHIR eCR standard is an electronic Reporting and Surveillance Distribution (eRSD) transaction to share trigger codes and reporting guidance in computable form via a subscription and polling service.
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 a 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 PHAs 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 PHAs 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.

### 1.10.1 Design Considerations

The Electronic Case Reporting (eCR) standards, the electronic Initial Case Report (eICR) and the Reportability Response (RR), support two broad approaches to eCR.

One of the approaches also uses the RCKMS on the AIMS platform to report to PHAs and one does not. The two approaches are:

1. Information flowing from healthcare to PHAs (via the eICR) and back (via the RR) after a reportability determination has been made at the healthcare organization using reporting rules from all PHAs for all conditions.
2. Information flowing from healthcare to a shared services platform (via the eICR) and then to PHAs (via the eICR and the RR) and with a response to healthcare from the shared services platform (via the RR).

In some jurisdictions, HIEs and/or Health Information Networks may also be employed to securely move data between organizations including to and from a shared services platform.

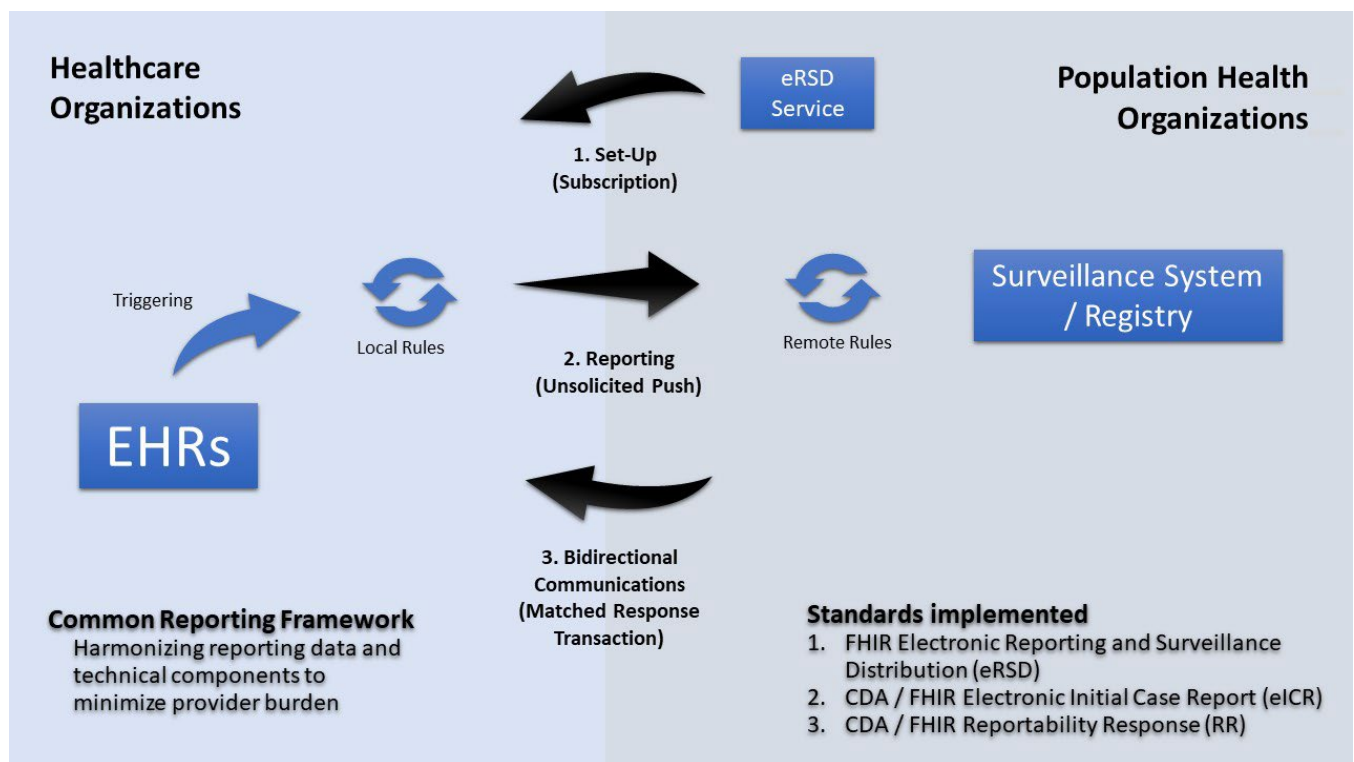
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<sup>[1]</sup> <http://hl7.org/fhir/us/ecr/history.html>

Prominent among these purposes is to implement public health reporting rules that cannot currently be readily distributed to healthcare. The rules ensure that PHAs only get the data they are authorized to receive by state laws.

Without more complex reporting rules that are distributable to, and executable in, healthcare most PHAs will not use approach #1. Regardless of the approach, the fundamental elements of this reporting align with other reporting needs as per the diagram below.

**Figure 2: Reporting Design Pattern**



### 1.10.2 Using the eRSD (from the FHIR eCR IG)

FHIR enables several helpful capabilities for eCR. Because reportable events occur in healthcare without PHA knowledge and because PHAs do not have the authority to receive these data until they are deemed reportable, eCR requires an unsolicited push transaction. FHIR or other messaging and flexibility in multi-network transport will be needed to get data to state-level agencies. To the transactions associated with the approaches listed above, we have added a transaction for eRSD of RCTC value sets and other reporting guidance from public health to healthcare to support reporting from EHRs. This eRSD transaction is supported by FHIR services, but EHR users do not need to be using FHIR to access it.

The eRSD transaction needs to be able to help orchestrate this reporting which may span a broad spectrum from trigger codes in an EHR all the way to a healthcare-based API connected rules engine that is external to the EHR but operating inside of healthcare or at a healthcare Business Associate. To achieve this orchestration the eRSD resource needs to guide the Triggering, Rule Processing, Clinical Feedback, Creation of eICR, Routing and Sending components of eCR and interactions between them. For some time, much of the eRSD

transaction will provide structure to eCR as human consumable guidance. The most immediately machine processable components are the included trigger code value sets.

When distributable rules can be processed in most healthcare settings, there may be needs to distribute the rules, the trigger codes, and links to relevant on-line condition-specific information. The eRSD transaction can enable these distributions going forward as well as provide details for how critical elements, like report timing, of the reporting process should be implemented. It will also allow for a connection to separate efforts to develop clinical guidelines for public health conditions. Reporting and guidelines should utilize the same infrastructure and approaches where possible to minimize demands on EHRs.

eICRs shared from EHR interface are not definitively reportable. There are complex rules that also need to also be implemented to ensure that case reports meet state laws for submission. Examples of some of these rules follow.

**Table 2: Current Decision Logic Rule examples**

Rule Number	Rule Description	Data needed for rule to determine reportability
Rule 1	Pediatric influenza mortality reporting	age and condition
Rule 2	Staph Aureus with Vancomycin MIC > 4µg/ml	condition and drug sensitivity
Rule 3	Respiratory Syncytial Virus associated deaths in laboratory confirmed cases less than five years of age	condition, cause of death, and age

## 1.11 Contents of the Package

The following files comprise this implementation guide package:

**Figure 3: Contents of the Package**

Filename	Description	Standards Applicability: Normative	Standards Applicability: Informative
CDAR2_IG_PHCASERPT_E4_S4_Vol1_Introductory_Material	Implementation Guide Introductory Material	Chapter 1 Chapter 4 Chapter 5 Appendix A Appendix B Appendix C	Chapter 2 Chapter 3 Chapter 6
CDAR2_IG_PHCASERPT_E4_S4_Vol2_Templates_and_Supporting_Material	Implementation Guide Template Library and Supporting Material	Templates Appendixes	Examples

Filename	Description	Standards Applicability: Normative	Standards Applicability: Informative
CDAR2_IG_PHCASERPT_E4_S4_SAMPLE.xml CDAR2_IG_PHCASERPT_E4_S4_SAMPLE_MANUAL.xml CDAR2_IG_PHCASERPT_E4_S4_SAMPLE_EXTERNAL_ENCOUNTER.xml (located on HL7 GitHub – see link below)	Automatically initiated eICR Sample file  Manually initiated eICR Sample File  External encounter eICR Sample File	n/a	Sample file
CDAR2_IG_PHCASERPT_E4_S4_SCHEMATRON.sch (located on HL7 GitHub - see link below)	Schematron rules for validation	n/a	Schematron file
CDAR2_IG_PHCASERPT_E4_S4_VOCABULARY.xml (located on HL7 GitHub - see link below)	Vocabulary for use by Schematron	n/a	XML file
HL7 GitHub link: <a href="https://github.com/HL7/CDA-phcaserpt/tree/main/CDA-phcaserpt-4.0.0">https://github.com/HL7/CDA-phcaserpt/tree/main/CDA-phcaserpt-4.0.0</a>	XML and Related files (Schematron, sample, html)	n/a	XML and related files
GitHub link: <a href="#">CDA Schema</a>			
_readme.txt	Text file describing contents of the package	n/a	Readme file

**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 eCR flow as depicted in the Context Use Case diagrams (Figures 4 and 5) below is also referenced in the Use Case Assumptions as well as the Pre-Conditions and Post-Conditions sections of this chapter. The broader eCR picture is included both to show how the electronic Initial Case Report fits in eCR and highlight important components that should be addressed in future work.

### 2.1 Context Use Case Flow Diagram

The diagram below shows the context for the overall flow of eCR, including where creation of the electronic Initial Case Report fits within the flow.

The left side of the eCR Context flow diagram shows (Figure 4) the generation and sending of the eICR including:

- The eICR is manually initiated by a provider.
- The eICR is automatically initiated based on a comparison of electronic health record data for an encounter against codes in a “trigger code file” provided by public health. This method requires a second level of decision support to determine relevant PHAs and make a determination on reportability.
- The eICR created and sent from an EHR system.
- The eICR created in an EHR and sent through a designee of clinical care, such as an HIE or trust network.

The center section, “Functions of eCR Decision Support and Interorganizational Exchange”, shows the functions that need to occur in order for a Reportability Response to be constructed and routed appropriately. Some of these functions could be operationalized by clinical care, public health, or one or more intermediaries (such as health information exchange organizations, clinical trust networks, or other shared services platforms).

“Determine Reportability for eICR Condition(s) for each Responsible Agency(ies)” is a function to determine if possible condition(s) in the eICR meet jurisdictional reporting requirements and to which responsible agency(ies) the eICR should be sent. This function could be met by:

- A centralized decision support service that is designed to include reporting specifications for all PHAs and all conditions and operates on behalf of the healthcare organization to operationalize reporting
- A localized decision support service operating under HIPAA Treatment, Payment and Operations
- Manual inspection (not recommended as reports may not meet reporting requirements) at a PHA in the absence of an automated approach

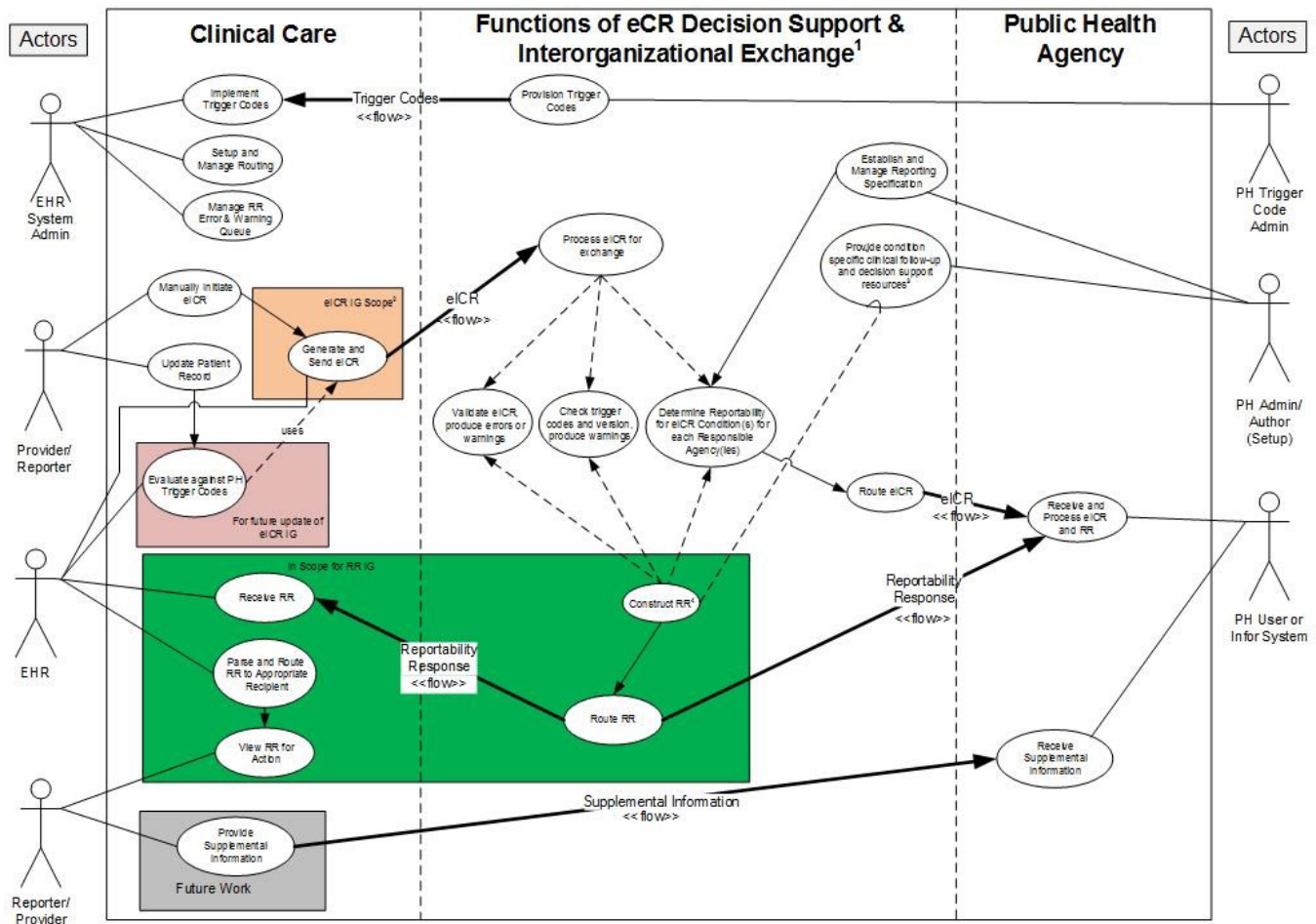
Once generated, the Reportability Response will be sent to the eICR originating clinical care organization and to a PHA, if generated by an intermediary. Once received by clinical care, the following may take place:

- The Reportability Response will be parsed and routed to the appropriate recipient
- The Reportability Response could be reviewed for action by a provider and/or a reporter
- Errors and warnings associated with the Reportability Response should be managed

The right side of the eCR Context flow diagram shows:

- The eICR is received by the PHA.
- The PHA receives the Reportability Response from an intermediary.
- The PHA receives Supplemental data from clinical care (future scope).

**Figure 4: Electronic Case Reporting Context Flow Diagram Reporting to a Public Health Agency**



<sup>1</sup> Some or all of these functions may be operationalized by:

- one or more intermediaries (such as health information exchange organizations, clinical trust networks, or other shared services platform);
- clinical care; and/or
- PHAs, under the authority of clinical care, public health, or a combination thereof.

## 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 public health 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 public health 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.
- Intermediary systems (e.g., HIEs, trust networks, a shared public health platform), if used, are responsible for passing transport-level acknowledgements with those that they connect to. There may be several “hops” between the EHR system and the public health information system. Where possible, Reliable Messaging will be helpful for supporting this transport.
- These transport level-acknowledgments may not pass through multiple hops and as such may not be considered an authoritative acknowledgement.

## 2.3 Pre-Conditions

The following have occurred:

- An authoritative set of reportable condition trigger codes, as provided and defined by Public Health (i.e., the RCTC trigger codes in the electronic Reporting and Surveillance Distribution (eRSD)– [ersd.aimsplatform.org](https://ersd.aimsplatform.org)) is implemented and accessed by the EHR system to match against encounter records.
- 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 public health is stored within the authoring system at the EHR.
- A record of receipt of the eICR is recorded in a log in the PHA system.
- The Reportability Response use case components, represented in that standard and implementation guide, are invoked.

## 2.5 Actors and Roles

**Figure 5: The actors and a description of their roles are included in the table below**

Actor	Role
Provider (Clinical care provider)	<ul style="list-style-type: none"> <li>• Has clinical responsibility for the patient in question</li> <li>• May be the clinician of record for the patient</li> <li>• Has responsibility for reporting to public health as appropriate</li> <li>• Update information in the EHR System about the patient</li> <li>• Serve as a possible recipient of the Reportability Response</li> <li>• The provider and the reporter may be the same person</li> <li>• If desired, initiate sending of eICR and provide reason for initiation (manual initiation)</li> <li>• Either directly or through a Reporter, provide follow-on information to PHA if requested</li> </ul>
EHR	<ul style="list-style-type: none"> <li>• Collect, receive, and/or store data on a patient record</li> <li>• Consume and maintain trigger codes</li> <li>• Match trigger code and generate eICR</li> <li>• Create report and transport to public health</li> <li>• Receive, route, and render the Reportability Response from public health</li> <li>• Make eICR available with associated Reportability Response when requested</li> <li>• Maintain a work queue (e.g., inbox) for Reportability Responses that require follow-on action</li> <li>• Facilitate capture of manually flagged conditions to be reported in an eICR</li> </ul>

Actor	Role
EHR System Administrator	<ul style="list-style-type: none"> <li>• Insure that eICRs are being properly triggered and that there is a Reportability Response received for each eICR transmitted</li> <li>• Monitor Reportability Response errors and warnings for issues with trigger codes and/or eICR creation and transmission</li> <li>• Configure any routing and/or applicable follow-on processing for Reportability Response requiring action with the receiving EHR system</li> </ul>
Reporter (Public Health Reporter)	<ul style="list-style-type: none"> <li>• May be a clinical or administrative staff person that supports the provider or an infection control practitioner</li> <li>• May have delegated responsibility for reporting to public health</li> <li>• Executes reporting responsibilities</li> <li>• Serve as a possible recipient of the Reportability Response</li> <li>• The provider and the reporter may be the same person</li> </ul>
PHA User or Information System	<ul style="list-style-type: none"> <li>• Receive and process eICR from EHR system or intermediary</li> <li>• If requested, receive and process Reportability Response</li> <li>• Receive and process supplemental information provided by Provider or Reporter</li> <li>• Use the information contained in the PHA system to carry out public health surveillance and investigation activities</li> </ul>
Public Health Jurisdiction User	<ul style="list-style-type: none"> <li>• The person in a PHA that uses the information contained in the PHA system</li> </ul>
Public Health Admin/Author (Setup)	<ul style="list-style-type: none"> <li>• As set-up steps for public health decision support,</li> <li>• Establish and manage reporting specifications</li> <li>• Provide condition-specific clinical follow-up and other decision support resources</li> </ul>
Public Health electronic Reporting and Surveillance Distribution / Trigger Code Admin	<ul style="list-style-type: none"> <li>• Identify and maintain set of trigger codes and other reporting guidance to be used in an EHR for comparison of electronic health record data for an encounter against these codes</li> <li>• Publish eRSD / trigger code set (on a routine schedule and/or for emergent situations)</li> </ul>
Clinical Care (or Clinical Care and Designee)	<ul style="list-style-type: none"> <li>• Implementer and user of EHR System; or</li> <li>• As designee of clinical care (e.g., HIEs):</li> <li>• Receive eICR from EHR system and send to Intermediary or PHA system</li> </ul>
Public Health Agency (or PHA and Intermediary)	<ul style="list-style-type: none"> <li>• Recipient of eICR from EHR system or clinical care designee</li> <li>• Confirmer of reportability</li> <li>• And if at public health intermediary, sender of eICR to PHA system</li> </ul>

Several functions can be supported by different actors to fulfill the following roles:

- Receive and process eICR from EHR system or other intermediary to:
  - Validate eICR
  - Check for valid trigger codes and current version
  - Determine reportability status using predefined jurisdiction- and condition-specific rules

- Send the eICR and Reportability Response (when requested) to identified PHAs based on public health decision support
- Construct the Reportability Response
- Send the Reportability Response to the EHR system or its intermediary

The actors for “Functions of eCR Decision Support and Interorganizational Exchange” (as identified in the eCR Context flow diagram) could be:

- One or more intermediaries (such as health information exchange organizations, clinical trust networks, or other shared services platforms)
- Clinical care
- PHAs, under the authority of clinical care, public health, or a combination thereof.

## 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 most 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 should be reviewed against all PHA reporting requirements to confirm reportability. 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.

When determined reportable, the eICR is received by one or more appropriate PHAs a Reportability Response is returned to the sending EHR system. The Reportability Response includes the confirmation of reportability, information about the responsible PHA(s), and over time, a request for supplemental information about the event if needed and/or information about the status of disease in the community.

### **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 coded clinical diagnosis of varicella to the trigger codes, eICR processing is started, ultimately resulting in an eICR being generated and reviewed

against all PHA reporting requirements to confirm reportability before sending to the PHA with authority over Facility C.

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 to a public health jurisdiction(s), a Reportability Response is provided to the EHR system at Facility C. The eICR is sent to the PHA(s) and 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 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(s) 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 utilize methods such as 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]<sup>9</sup>. Clinical documents, according to CDA R2, have the following characteristics:

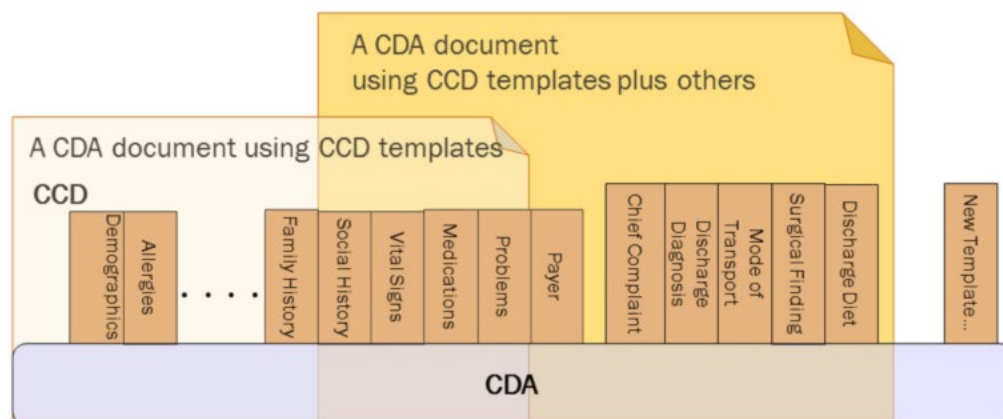
- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

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”<sup>10</sup> 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 6: Templated CDA R2**



<sup>9</sup> HL7 CDA Release 2. [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=7](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7)

<sup>10</sup> <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm>

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

- **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.FIELDDED) 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.

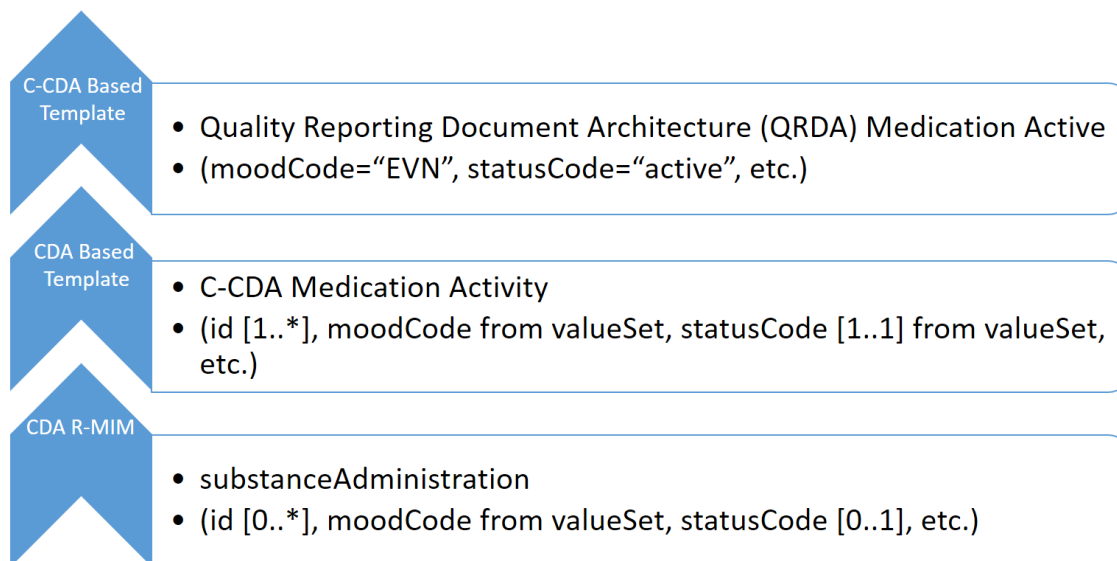
Regarding implementation, a CDA R2 instance populates the template identifier (`templateId`) field where it wants to assert conformance to a given template version. On the receiving side, the recipient can then not only test the instance for conformance against the CDA R2 Extensible Markup Language (XML) 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 RMIM) 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 RMIM) 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 7: 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.<sup>11</sup> 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.

**Figure 8: Initial Case Report Trigger Code Problem Observation Contexts**

Contained By:	Contains:
<a href="#">Encounter Diagnosis (V3)</a> (optional) <a href="#">Problem Concern Act (V3)</a> (optional)	

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

<sup>11</sup> Trifolia Workbench, <https://trifolia.lantanagroup.com/>

**Figure 9: 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		<a href="#">3284-317</a>	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		<a href="#">3284-318</a>	urn:oid:2.16.840.1.113883.11.20.9.25 (Planned moodCode (Observation))
templateId	1..1	SHALL		<a href="#">3284-311</a>	
@root	1..1	SHALL		<a href="#">3284-319</a>	2.16.840.1.113883.10.20.15.2.3.4
@extension	1..1	SHALL		<a href="#">3284-320</a>	2016-12-01
id	1..*	SHALL		<a href="#">3284-321</a>	
code	1..1	SHALL		<a href="#">3284-325</a>	urn:oid:2.16.840.1.113883.6.1 (LOINC)
@code	1..1	SHALL		<a href="#">3284-336</a>	urn:oid:2.16.840.1.113762.1.4.1146.1056 (Lab Order Test Triggers for Public Health Reporting (RCTC subset))
@sdtc:valueSet	1..1	SHALL		<a href="#">3284-337</a>	2.16.840.1.114222.4.11.7508
@sdtc:valueSetVersion	1..1	SHALL		<a href="#">3284-338</a>	

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** (CONF:81-7899) such that it
  - a. **SHALL** contain exactly one [1..1]
   
**@root="2.16.840.1.113883.10.20.22.4.31"** (CONF: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 10: Constraints Format Example**

### Initial Case Report Trigger Code Lab Test Order (V2)

[observation: identifier

urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.4:2019-04-01 (open)]

Draft as part of Public Health Case Report, Release 1, STU Release 2 - 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:4411-317).
3. **SHALL** contain exactly one [1..1] @moodCode="RQO" Request (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 **STATIC**) (CONF:4411-318).
4. **SHALL** contain exactly one [1..1] templateId (CONF:4411-311) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.15.2.3.4" (CONF:4411-319).
  - b. **SHALL** contain exactly one [1..1] @extension="2019-04-01" (CONF:4411-320).

The trigger code may be contained in either the code element or the code/translation element. One of code or code/translation **SHALL** contain @sdtc:valueSet and @sdtc:valueSetVersion to flag that it is the element containing the trigger code.

5. **SHALL** contain exactly one [1..1] code, which **SHOULD** be selected from CodeSystem LOINC (urn:oid:2.16.840.1.113883.6.1) (CONF:4411-325).

Note: Lab order code

- a. This code **SHALL** contain exactly one [1..1] @code, which **SHOULD** be selected from ValueSet [Lab Order Test Name Triggers for Public Health Reporting \(RCTC subset\)](#) urn:oid:2.16.840.1.113762.1.4.1146.1056 **DYNAMIC** (CONF:4411-470).
- b. This code **SHOULD** contain zero or one [0..1] @sdtc:valueSet="2.16.840.1.114222.4.11.7508" (CONF:4411-471).
- c. This code **SHOULD** contain zero or one [0..1] @sdtc:valueSetVersion (CONF:4411-338).

Note: RCTC Definition Version used (e.g. 12/12/2018)
- d. This code **MAY** contain zero or more [0..\*] translation (CONF:4411-472).
  - i. The translation, if present, **SHALL** contain exactly one [1..1] @code, which **MAY** be selected from ValueSet [Lab Order Test Triggers for Public Health Reporting \(RCTC subset\)](#) urn:oid:2.16.840.1.113762.1.4.1146.1056 **DYNAMIC** (CONF:4411-473).
  - ii. The translation, if present, **MAY** contain zero or one [0..1] @sdtc:valueSet="2.16.840.1.114222.4.11.7508" (CONF:4411-474).

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 Implementation Guide 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 implementation guide 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 implementation guide illustrate the optional use of the C-CDA R1.1 templateId:

**Figure 11: 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 STU2] Initial Case Report Trigger Code Problem Observation (V2) -->
  <templateId extension="2019-01-01" 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*.<sup>12</sup>

**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...

<sup>12</sup> HL7, *Version 3 Publishing Facilitator's Guide*. <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm>

- a. This structuredBody **SHOULD** contain zero or one [0..1] **component** (CONF: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) (CONF:1098-29067).

...is understood as:

- a. It is recommended (**SHOULD**) that the structuredBody 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** (CONF:1098-29086) such that it
  - 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) (CONF: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 12: Constraints Format – only one allowed**

1. **SHALL** contain exactly one [1..1] **participant** (CONF:2777).
  - a. This participant **SHALL** contain exactly one [1..1] **@typeCode="LOC"** (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF: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 13: Constraints Format – only one like this allowed**

1. **SHALL** contain exactly one [1..1] **participant** (CONF:2777) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="LOC"** (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF: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 14: 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.<sup>13</sup>

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 15: Attribute Required (`nullFlavor` not allowed)**

- |   |
|---|
| <p>1. <b>SHALL</b> contain exactly one [1..1] <code>code</code> (CONF:15407).</p> <p>a. This <code>code</code> <b>SHALL</b> contain exactly one [1..1] <code>@code="11450-4"</code> Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15408).</p> <p>or</p> <p>2. <b>SHALL</b> contain exactly one [1..1] <code>effectiveTime/@value</code> (CONF:5256).</p> |
|---|

<sup>13</sup> HL7 CDA Release 2. [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=7](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7)

**Figure 16: 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>
```

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 17: 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 18: 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, the Continuity of Care Document (CCD), IHE, and the Health Information Technology Standards Panel (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 19: 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 20: 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 21: Value Completely Unknown**

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

**Figure 22: 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 23: Binding to a Single Code**

**2. SHALL** contain exactly one [1..1] **code** (CONF:15403).  
a) This code **SHALL** contain exactly one [1..1] **@code**="11450-4" Problem List (CONF: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**) (CONF: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 24: 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*<sup>14</sup> 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.

<sup>14</sup> HL7 Version 3 Interoperability Standards, Normative Edition 2010.

<http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010>

**Figure 25: 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.

**Figure 26: 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: <a href="http://www.ietf.org/rfc/rfc4646.txt">http://www.ietf.org/rfc/rfc4646.txt</a>			
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** (CONF: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) (CONF: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" (CONF: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 Reference Information Model (RIM) classes, this document uses XML Path Language (XPath) notation<sup>15</sup> in conformance statements and elsewhere to identify the 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.

---

<sup>15</sup> XML Path Language. <http://www.w3.org/TR/xpath/>

**Figure 27: 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 28: XPath Expression Example**

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

## 4.2.2 XML Examples and Sample Documents

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.

**Figure 29: ClinicalDocument Example**

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

This publication package includes complete XML sample documents as listed in the [Contents of the Package](#) table. Please note that all XML examples and sample documents included with the implementation guide are not normative, therefore implementers should rely on the implementation guide content in normative sections of the implementation guide for specific conformance guidance. The examples and samples represent one of many examples of a valid eICR.

## 5 EICR IMPLEMENTATION GUIDE 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 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) or *C-CDA Templates for Clinical Notes STU Companion Guide Release 4.1* (C-CDA CG R4.1).

The electronic Initial Case Report Document (eICR) (V6) template is unique to this guide and establishes the document header for the eICR document type. This header extends the C-CDA CG R4.1 US Realm Header (V4) 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), pregnancy templates that are part of *C-CDA R2.1 Supplemental Templates for Pregnancy Status, Release 1*, and occupation templates that are part of *C-CDA Templates for Clinical Notes; Occupational Data for Health (ODH) Release 1*. It also includes CDA R2 templates created for this IG: Country of Nationality Observation, Country of Residence Observation, Disability Status Observation, Emergency Outbreak Information Observation, Exposure/Contact Information Observation, Purpose of Travel Observation, Therapeutic Medication Response Observation, Transportation Details Observation, Transportation Details Organizer, Travel History, Tribal Affiliation Observation, and Vaccine Credential Patient Assertion.

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. Due to tooling limitations, the references to the non-included templates are still present in the containment tables and prose, but the clickable links to the templates are not present. In some cases the C-CDA entry templates have been updated in C-CDA CG but the C-CDA R2.1 section templates have not been updated to contain them. The C-CDA templates are backwards compatible and we recommend that implementers always include the templateId for both the C-CDA R2.1 template and for the C-CDA CG template to avoid any validation issues.

### 5.2 C-CDA Reuse and Conformance

Where C-CDA templates have been reused and not further constrained in this guide there are several cases where the C-CDA containment constraints templates use the **MAY** conformance verb. For example, C-CDA states that the Encounter Activity (V3) **MAY** contain an Encounter Diagnosis (V3). For the purpose of this implementation guide, a select set of these conformance verbs are to be interpreted as **SHOULDs**, i.e. *if the data is available it must be included*. The following is a table of the selected C-CDA containments:

**Figure 30: “SHOULD” eICR Conformance for Selected C-CDA Containments**

Containing C-CDA Template	Contained C-CDA Template	Conformance Number
Encounter Activity (V3)	Encounter Diagnosis	1198-15492
Medications Administered Section (V2)	Medication Activity	1098-8153
Past Medical History (V3)	Problem Observation (V3)	1198-8791
Plan of Treatment Section (V2)	Planned Act (V2)	1098-30473
Plan of Treatment Section (V2)	Planned Immunization Activity	1098-32354
Plan of Treatment Section (V2)	Planned Medication Activity (V2)	1098-8811
Plan of Treatment Section (V2)	Planned Observation (V2)	1098-7726
Plan of Treatment Section (V2)	Planned Procedure (V2)	1098-30474
Pregnancy Section	Last Menstrual Period (V2)	3368-26531
Pregnancy Section	Postpartum Status	3368-26623
Social History Section (V2)	Characteristics of Home Environment	1198-28826
Social History Section (V2)	Pregnancy Observation	1198-9132
Social History Section (V2)	Social History Observation (V3)	1198-7953

### 5.3 Stand-Alone Templates

For some templates in this IG, a different template-containment referencing method is used - one in which only optional templates are referenced. This approach is intended to reduce the impact of adding new templates to already-published specifications. Traditionally, adding a new template to an implementation guide has triggered a “bubble-up” versioning effect, requiring every containing template in the hierarchy - up to the top-level document template - to be versioned. (See [Template Versioning](#).) This process places a significant burden on both specification authors and implementers, as many templates beyond the one being revised must be updated.

With the alternative containment-referencing method, new templates are created as stand-alone entities. Their usage is defined within the template’s own description rather than through explicit constraints in the containing template(s). Because most CDA R2 templates are open templates (see [Open and Closed Templates](#)), a template does not need to explicitly reference another template in order to contain it.

The following excerpt from a template definition illustrates this method:

**Figure 31: Stand-Alone Template Example**

### Initial Case Report Trigger Code Lab Test Order (V2)

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.4:2019-04-01 (open)]

Draft as part of Public Health Case Report, Release 2 - the Electronic Initial Case Report (eICR), STU Release 2.0 - US Realm

**Figure 32: Initial Case Report Trigger Code Lab Test Order Contexts**

Contained By:	Contains:
<a href="#">Plan of Treatment Section (V2)</a> (optional)	

This template is designed for optional [0..\*] use in the Plan of Treatment Section (V2) contained in an Initial Public Health Case Report Document (eICR) (V2). This template MAY be included zero or more times [0..\*] in the Plan of Treatment Section (V2).

The *Initial Case Report Trigger Code Lab Test Order* indicates that the observation code is a trigger code contained in the [Reportable Condition Trigger Codes table](#). If the observation code is a trigger code, this template must be present.

...

## 5.4 Trigger Code Templates

Reportable condition trigger codes are contained in the Reportable Condition Trigger Codes (RCTCs) in the eRSD and available at [ersd.aimsplatform.org](https://ersd.aimsplatform.org) <sup>16</sup>.

The eICR implementation guide 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 templates are as follows:

- Initial Case Report Trigger Code Problem Observation (V3)  
[urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.3:2021-01-01]
- Initial Case Report Trigger Code Result Observation (V2)  
[urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.2:2019-04-01]
- Initial Case Report Trigger Code Lab Test Order (V2)  
[urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.4:2019-04-01]
- Initial Case Report Trigger Code Medication Information  
[urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.36:2019-04-01]
- Initial Case Report Trigger Code Result Organizer  
[urn:hl7ii: 2.16.840.1.113883.10.20.15.2.3.35:2019-04-01]

<sup>16</sup> <https://ersd.aimsplatform.org>

The trigger code templates are eICR implementation guide templates. They are based on C-CDA R2.1 templates and follow the principles described in [Further Constraining Existing Templates](#) and [C-CDA Reuse and Conformance](#)

Where C-CDA templates have been reused and not further constrained in this guide there are several cases where the C-CDA containment constraints templates use the **MAY** conformance verb. For example, C-CDA states that the Encounter Activity (V3) **MAY** contain an Encounter Diagnosis (V3). For the purpose of this implementation guide, a select set of these conformance verbs are to be interpreted as **SHOULDs**, i.e. *if the data is available it must be included*. The following is a table of the selected C-CDA containments:

**Figure 30: “SHOULD” eICR Conformance for Selected C-CDA Containments**

Containing C-CDA Template	Contained C-CDA Template	Conformance Number
Encounter Activity (V3)	Encounter Diagnosis	1198-15492
Medications Administered Section (V2)	Medication Activity	1098-8153
Past Medical History (V3)	Problem Observation (V3)	1198-8791
Plan of Treatment Section (V2)	Planned Act (V2)	1098-30473
Plan of Treatment Section (V2)	Planned Immunization Activity	1098-32354
Plan of Treatment Section (V2)	Planned Medication Activity (V2)	1098-8811
Plan of Treatment Section (V2)	Planned Observation (V2)	1098-7726
Plan of Treatment Section (V2)	Planned Procedure (V2)	1098-30474
Pregnancy Section	Last Menstrual Period (V2)	3368-26531
Pregnancy Section	Postpartum Status	3368-26623
Social History Section (V2)	Characteristics of Home Environment	1198-28826
Social History Section (V2)	Pregnancy Observation	1198-9132
Social History Section (V2)	Social History Observation (V3)	1198-7953

Stand-Alone Templates. These templates further constrain C-CDA R2.1 templates as follows:

C-CDA R2.1 Template	eICR Trigger Code Template
Immunization Medication Information (V2)	Initial Case Report Trigger Code Immunization Medication Information
Medication Information (V2)	Initial Case Report Trigger Code Medication
Planned Act (V2)	Initial Case Report Trigger Code Planned Act
Planned Observation (V2)	Initial Case Report Trigger Code Lab Test Order (V2)
Problem Observation (V3)	Initial Case Report Trigger Code Problem Observation (V3)
Result Observation (V3)	Initial Case Report Trigger Code Result Observation (V2)
Result Organizer (V3)	Initial Case Report Trigger Code Result Organizer

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 either `code`, `value[xsi:type="CD"]`, or both to the RCTC table (value set)
- either `code/@sdct:valueSet` or `code/translation/@sdct:valueSet` must be present in order to capture the RCTC table OID (2.16.840.1.114222.4.11.7508)
  - if `code/@sdct:valueSet` is present: `code/@sdct:valueSetVersion` must be present in order to capture the RCTC definition version.
  - if `code/translation/@sdct:valueSet` is present: `code/translation/@sdct:valueSetVersion` must be present in order to capture the RCTC definition version.
  - if `value[xsi:type="CD"]/@sdct:valueSet` is present: `value[xsi:type="CD"]/@sdct:valueSetVersion` must be present in order to capture the RCTC definition version.
  - if `value[xsi:type="CD"]/translation/@sdct:valueSet` is present: `value[xsi:type="CD"]/translation/@sdct:valueSetVersion` must be present in order to capture the RCTC definition version.
- Set `negationInd` to true when a trigger code was previously entered in error and has now been corrected. A `negationInd` of true is not making a statement that the act/observation/procedure, etc. has not happened, rather that this trigger code data was entered in error.

Initial Case Report Trigger Code Problem Observation only:

- require `@negationInd` with the following requirements:
  - Set `negationInd` to false where there is a triggering code.
  - The only time `negationInd` should be set to true is when a trigger code has been entered in error and is now being fixed in the system. A `negationInd` of true is not making a statement that the patient does not have the condition, rather that this trigger code data was entered in error.

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

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

**Figure 33: Initial Case Report Trigger Code Problem Observation (V3) Constraints Overview**

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.3:2021-01-01)					
@classCode	1..1	SHALL		<a href="#">4482-183</a>	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		<a href="#">4482-184</a>	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
@negationInd	1..1	SHALL		<a href="#">4482-296</a>	
templateId	1..1	SHALL		<a href="#">4482-157</a>	
@root	1..1	SHALL		<a href="#">4482-169</a>	2.16.840.1.113883.10.20.15.2.3.3
@extension	1..1	SHALL		<a href="#">4482-170</a>	2021-01-01
value	1..1	SHALL	CD	<a href="#">4482-160</a>	
@code	1..1	SHALL		<a href="#">4482-176</a>	urn:oid:2.16.840.1.113762.1.4.1146.627 (Diagnosis_Problem Triggers for Public Health Reporting (RCTC subset))
@sdtc:valueSet	0..1	SHOULD		<a href="#">4482-187</a>	2.16.840.1.114222.4.11.7508
@sdtc:valueSetVersion	0..1	SHOULD		<a href="#">4482-188</a>	
translation	0..*	MAY		<a href="#">4482-476</a>	
@code	1..1	SHALL		<a href="#">4482-477</a>	urn:oid:2.16.840.1.113762.1.4.1146.627 (Diagnosis_Problem Triggers for Public Health Reporting (RCTC subset))
All @sdtc:valueSet	0..1	MAY		<a href="#">4482-478</a>	2.16.840.1.114222.4.11.7508
@sdtc:valueSetVersion	0..1	MAY		<a href="#">4482-479</a>	

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 RCTC value set, as seen in the following example:

**Figure 34: RCTC Value Set Example**

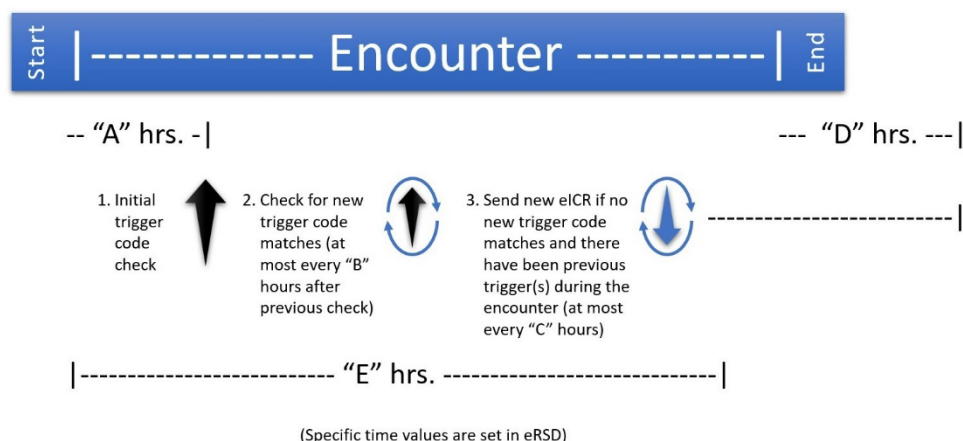
```
<code code="11585-7"
  codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC"
  displayName="Bordetella pertussis Ab [Units/volume] in Serum"
  sdtc:valueSet="2.16.840.1.114222.4.11.7508"
  sdtc:valueSetVersion="2020-11-13" />
```

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., 2020-11-13) recorded in code/@sdtc:valueSetVersion.

## 5.5 Automatically Initiated eICR Documents

eICR documents will usually be automatically initiated by matching EHR data against trigger codes. The following figure illustrates automatic initiation by trigger matching:

### eICR Triggering and Transmission Timing



**Figure 35: eICR Triggering and Transmission Guidance**

## 5.6 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 from the eRSD.

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 eICR implementation guide template is based on the C-CDA R2.1 Problem Observation (V3) template and follows the principles described in [Further Constraining Existing Templates](#) and [C-CDA Reuse](#) and Conformance

Where C-CDA templates have been reused and not further constrained in this guide there are several cases where the C-CDA containment constraints templates use the **MAY** conformance verb. For example, C-CDA states that the Encounter Activity (V3) **MAY** contain an Encounter Diagnosis (V3). For the purpose of this implementation guide, a select set of these conformance verbs are to be interpreted as **SHOULDs**, i.e. *if the data is available it must be included*. The following is a table of the selected C-CDA containments:

**Figure 30: “SHOULD” eICR Conformance for Selected C-CDA Containments**

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Plan of Treatment Section (V2)	Planned Act (V2)	1098-30473
Plan of Treatment Section (V2)	Planned Immunization Activity	1098-32354
Plan of Treatment Section (V2)	Planned Medication Activity (V2)	1098-8811
Plan of Treatment Section (V2)	Planned Observation (V2)	1098-7726
Plan of Treatment Section (V2)	Planned Procedure (V2)	1098-30474
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Social History Section (V2)	Characteristics of Home Environment	1198-28826
Social History Section (V2)	Pregnancy Observation	1198-9132
Social History Section (V2)	Social History Observation (V3)	1198-7953

Stand-Alone Templates.

## 5.7 Alternate Initiation of eICR Documents

When the serviceEvent in the CDA Header is present with a code of "PHC2235: Alternately Initiated eICR", it indicates that this eICR document was initiated by automated process and is intended to force reporting to the responsible PHA for the jurisdiction of care.

Unlike eICRs manually initiated by a provider, which are force reported to all relevant jurisdictions, PHC2235 will be sent to, and only to, the PHA of the jurisdiction of care. If a reportable condition is found by public health decision support then the alternately initiated eICR may also be reported to the jurisdiction of residence PHA.

eICR documents will usually be automatically initiated by matching EHR data against trigger codes. There are some circumstances, however, where they may be manually initiated by providers of care because they suspect there may be a reportable condition. And they may also be alternately initiated by automated, forced reporting by the EHR to meet short term reporting needs. The following matrix illustrates these different types of initiation:

**Table 3: Initiation Table**

<b>Initiation Type</b>	<b>How Is the eICR initiated?</b>	<b>How is the eICR routed on a shared services platform</b>	<b>Initial Case Report Initiation Reason Observation (V2) template</b>	<b>serviceEvent/ code</b>	<b>Can values exist in eICR trigger code segments?</b>
Trigger code initiation	An EHR data match against a trigger code value	Reporting to relevant PHAs is based on public health decision support reportability determinations	Not included	Not included	Yes, one or more must be present
Manual initiation	By an action by a provider of care because they suspect there may be a reportable condition	Forced reporting to <u>all involved PHAs</u> regardless of reportability determinations	Includes free text or coded reason(s) for manual initiation	PHC1464	Yes, if the EHR checks for matches after manual initiation or if the match precedes manual initiation  (However, they may not exist).
Alternate initiation	EHR / healthcare site "programmed-in" initiation to meet transient need	Forced reporting to <u>the PHA where care was provided</u> regardless of reportability determinations. Reporting to other jurisdictions may occur if other conditions are present.	Includes free text or coded reason(s) for alternate initiation	PHC2235	Yes, if EHR checks for matches after alternate initiation or if the match precedes alternate initiation  (However, they may not exist).

#### **Alternate Initiation Scenario 1: Parkinson's Reporting Registry**

An eICR is alternatively initiated and force-reported to the PHA where care was provided. No other reportable conditions are present, so no additional reporting to other PHAs occurs.

#### **Alternate Initiation Scenario 2: Parkinson's Reporting Registry**

An eICR is alternatively initiated and force-reported to the PHA where care was provided. Another reportable condition is present and is identified after the alternate initiation, triggering reporting to all relevant PHAs.

## 5.8 Relevant Time Period for Retrieving Data

Data	Time Period
Occupation	Data capturing during current encounter
Immunization	Full history
Pregnancy	Past year
Vital Signs	Current encounter
Travel History	Past year
Problems/Conditions	Current encounter
Medications	Current encounter
Procedures	Current encounter

## 5.9 Section-Level Confidentiality Codes

It is possible to set a confidentiality code at the section level - this overrides the value propagated from the StructuredBody and allows the setting of restricted access to all the data elements in a section (e.g.: information about other people). The values allowed are:

- N (normal): Normal confidentiality rules (according to good health care practice) apply. That is, only authorized individuals with a legitimate medical or business need may access this item.
- R (restricted): Restricted access, e.g., only to providers having a current care relationship to the patient.
- V (very restricted): Very restricted access as declared by the Privacy Officer of the record holder.

## 5.10 Value Set Guidance

### 5.10.1 Specimen Type (urn:oid:2.16.840.1.113883.21.327)

This value set is used in the Specimen Participant (ID) template to specify the type of specimen. This is a grouping value set that contains HL70487 codes and all the codes from the SNOMED CT Specimen hierarchy (123038009 - This concept and all its descendants in the specimen hierarchy. A cross-mapping table exists between SNOMED CT codes and the HL70487 codes - care should be taken to use either one or the other in the negotiated value set, so that each concept is represented ONLY once).

### 5.10.2 Medication Clinical Drug (urn:oid: 2.16.840.1.113762.1.4.1010.4)

This value set is used in the Medication Information (V2) template. The constraint that binds this data element states that the code SHALL be from the Medication Clinical Drug value set. The definition for that value set lists the types of RxNorm codes that are allowed. The Schematron in the validator does not check the code as it is a DYNAMIC binding to the value set, and it is the responsibility of the implementer to ensure that the values that are used are from the correct value set. An eICR would not get rejected if the value was not in the value set.

## 5.11 Null Values and the eICR IG

The constraint of “SHALL” has been applied to the majority of data elements identified in Section [eICR 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 PHA 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 (ClinicalDocument/effectiveTime) (CONF:4411-141)
- Facility Type  
(ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/code) (CONF:4411-14)
  - A nullFlavor is not allowed when the location is present, however, in the case of an External Encounter, the location may not be present.
- Visit Date/Time (CONF:4411-5)
  - A nullFlavor is not allowed on the effectiveTime data element, however, in the case of an External Encounter, a nullFlavor may be used in the required effectiveTime/low (PatientEncounter.fromDateTime) element.

## 6 EICR DATA REQUIREMENTS

### 6.1 eICR Data Requirements

The Council of State and Territorial Epidemiologists (CSTE) has reviewed and deemed appropriate the content of the electronic initial case report (eICRs) standards for a multi-condition, multi-jurisdiction electronic case report, and stipulated the following (CSTE letter of November 1st, 2021):

*Public Health Agencies (PHAs) are authorized to receive the data specified in the electronic initial case report (eICR) as a multi-condition, multi-jurisdiction electronic case report. When these data are available, they should be used to populate eICRs transmitted from electronic health records (EHRs).*

*There may be additional data, also needed by public health, that may be requested by public health agencies subsequent to the receipt of an eICR that are necessary for public health investigation that should also be shared in accordance with state and local laws and regulations. Public health agencies are authorized by such laws and regulations to investigate and receive data for cases of reportable disease, whether suspected or confirmed.*

**Figure 36: eICR Data Elements**

eICR ELEMENT NAME	eICR 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 PHA 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	Identifier of the provider responsible for the patient's care when the case was triggered(e.g., National Provider Identifier (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	Name of the provider responsible for the patient's care when the case was triggered	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Provider Phone	A phone number for the provider responsible for the patient's care when the case was triggered	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.

<b>eICR ELEMENT NAME</b>	<b>eICR DESCRIPTION</b>	<b>RATIONALE / JUSTIFICATION</b>
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 Address	The provider's geographical location or mailing address.	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Provider Facility/Office Name	The name of the office or facility of the provider responsible for the patient's care when the case was triggered (where care was provided to the patient).	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Provider Facility/Office Address	The address of the office or facility of the provider responsible for the patient's care when the case was triggered (where care was provided to the patient).	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Provider Facility/Office Telecom	The telecom of the office or facility of the provider responsible for the patient's care when the case was triggered (where care was provided to the patient).	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Facility ID	Identification code for the facility (e.g., Facility NPI) in which care was provided	Need contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Facility Address	The physical location of the facility in which care was provided when the case was triggered	Need contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Facility Name	The name of the facility in which care was provided when the case was triggered	Need 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

<b>eICR ELEMENT NAME</b>	<b>eICR DESCRIPTION</b>	<b>RATIONALE / JUSTIFICATION</b>
Healthcare Organization Contact Name	The contact name for the for the umbrella organization under which the facility where care was provided operates	Need contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Healthcare Organization Id	Identification code for the umbrella organization under which the facility where care was provided operates	Need contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Healthcare Organization Contact Telecom	A contact telecom address (phone, email, fax, etc.) for the umbrella organization under which the facility where care was provided operates	Need contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Healthcare Organization Contact Address	The contact address for the umbrella organization under which the facility where care was provided operates	Need 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

<b>eICR ELEMENT NAME</b>	<b>eICR DESCRIPTION</b>	<b>RATIONALE / JUSTIFICATION</b>
Birth Date	The patient's date of birth	Appropriate identification, appropriate identification of minors, risk; Necessary to determine patient age; matching electronic laboratory reports (ELRs)
Patient Birth 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
Current Occupation	Occupation which the subject currently holds.	Identification of potential risk, transmission risk
Usual Occupation	The occupation which the subject has held for the longest duration through his or her working history.	Identification of potential risk, transmission risk
Current Industry	Type of business (industry) in which the subject currently holds a job.	Identification of potential risk, transmission risk
Usual Industry	The industry (type of business) which the subject has worked in for the longest duration while in the usual occupation	Identification of potential risk, transmission risk
Current Job Title	Title of the currently held job.	Identification of potential risk, transmission risk
Current Employer Name, Phone, and Address	Name, phone, and address of the current employer.	Identification of potential risk, transmission risk
Occupational Exposure	Actual contact or interaction with a specific hazard at work that increases an individual's risk of a detrimental physical or mental health outcome.	Identification of potential risk, transmission risk
History of Employment Status	Clinical statement about a person's relationship to working for pay, family earnings, or training (e.g. having one or more jobs, searching for work, etc.).	Identification of potential risk, transmission risk
Pregnancy status (yes, no, possible, unknown)	The patient's pregnancy status.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Pregnancy status determination method	The method by which the pregnancy status was determined.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment

<b>eICR ELEMENT NAME</b>	<b>eICR DESCRIPTION</b>	<b>RATIONALE / JUSTIFICATION</b>
Pregnancy status recorded date	The date on which the pregnancy status was recorded.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Estimated date of delivery (EDD)	Estimated date a woman will give birth.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Estimated date of delivery (EDD) method	The method used to determine the EDD.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Estimated gestational age	The estimated gestational age of the pregnancy (in contrast to the gestational age at birth), beginning from the time of fertilization.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Estimated gestational age determination date	The date the gestational age was determined.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Estimated gestational age determination method	The method used to determine the gestational age.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Last menstrual period (LMP)	Start date of the last menstrual period of the patient.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Pregnancy outcome	The result(s) of the pregnancy, such as live birth, still birth, miscarriage, etc.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Pregnancy outcome date	Date on which the pregnancy outcome occurred.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Postpartum status	The postpartum status of a patient. If the template is present, the patient is in the postpartum period.	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 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

<b>eICR ELEMENT NAME</b>	<b>eICR DESCRIPTION</b>	<b>RATIONALE / JUSTIFICATION</b>
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
Chief Complaint	Patient's chief complaint (the patient's own description)	An early indicator of a possible reportable condition
Past Medical History	A record of the patient's past complaints, problems, and diagnoses.	Provides information on patient's previous conditions or diagnoses that could be relevant to the current condition, such as underlying conditions.
Review of Systems	A relevant collection of symptoms and functions systematically gathered by a clinician (includes symptoms the patient is currently experiencing, some of which were not elicited during the history of present illness, as well as a potentially large number of pertinent negatives, for example, symptoms that the patient denied experiencing).	If clinical details signify a possible case of public health importance - confirm the need for public health follow up
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 public health importance - confirm the need for public health follow-up
Laboratory Order Code	Ordered tests for the patient during the encounter	Some lab test orders are reportable for suspected cases
Laboratory Result	The result of a laboratory test for the patient during the encounter	Some lab test results are reportable for suspected cases
Laboratory Result Status	The status of a laboratory test (preliminary, final etc.)	Indication of test completeness and reliability of results.
Specimen source/type/id/collection date	Information about the specimen collected	Additional details on laboratory specimen needed to confirm some conditions (e.g., collected from a sterile site)
Placer Order Number	Identifier for the laboratory order from the encounter	Potential value to linking electronic laboratory reports (ELR) to eICR

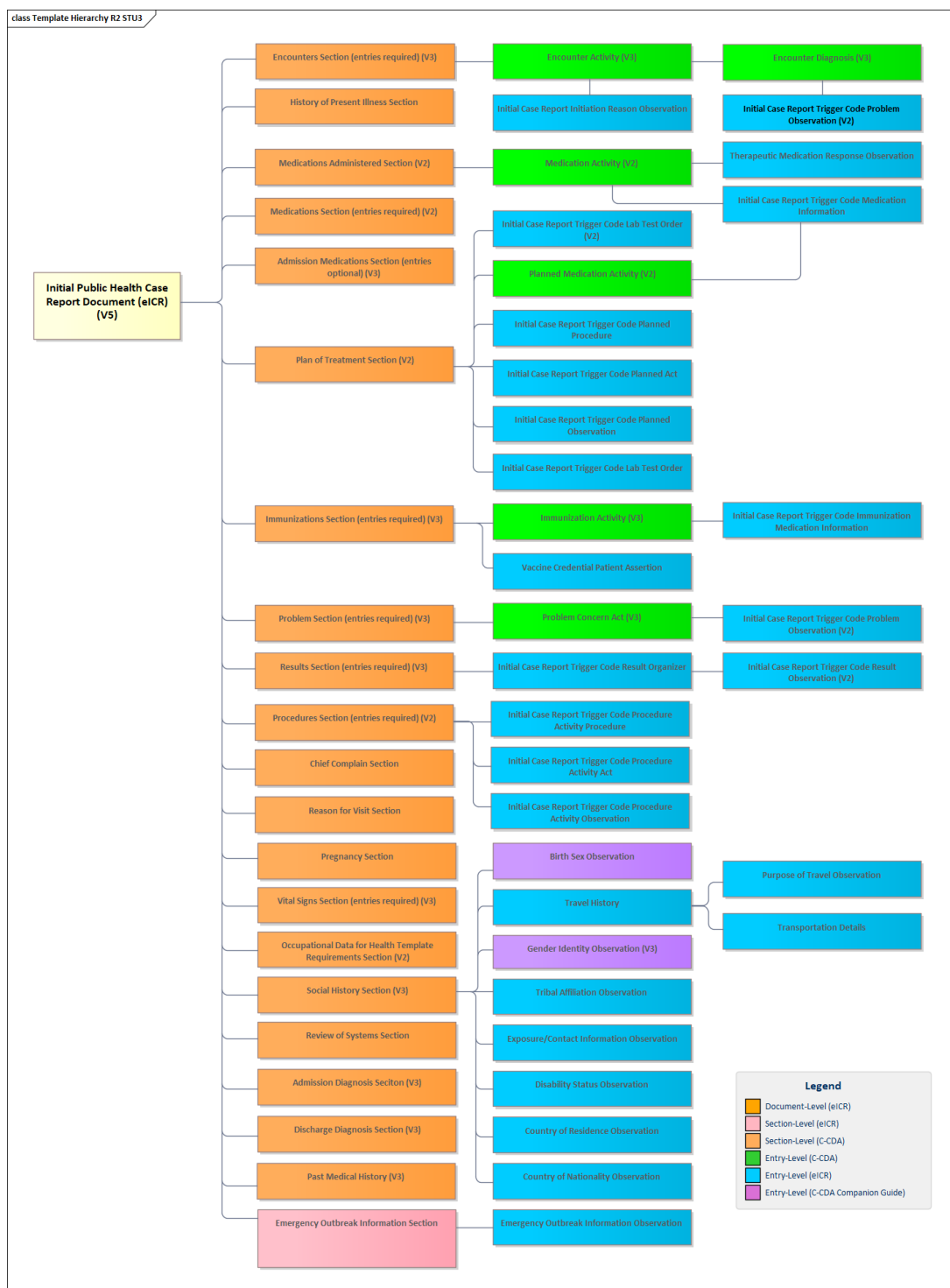
<b>eICR ELEMENT NAME</b>	<b>eICR DESCRIPTION</b>	<b>RATIONALE / JUSTIFICATION</b>
Diagnoses (list)	The healthcare provider's diagnoses of the patient's health condition (all)	If clinical diagnoses signify a case of public health importance - confirm the need for public health follow-up
Date of Diagnosis	The date of provider diagnosis	Knowing when patient is diagnosed; integral to epidemiological investigation
Medications	Medications relevant to the reportable event (includes admission, administered, historical, planned medications)	To find treatments that were prescribed; prophylaxis; knowing if the patient has already been treated, lower on the list for public health (priority)
Death Date	The patient's date of death	Patient follow-up and epidemiological purposes
Patient Class (Encounter Type)	Whether patient is outpatient, inpatient, emergency, urgent care	Indication of possible severity of condition
Travel History	The patient's travel history, includes purpose of travel, dates of travel, locations of travel, details of transportation (ship, plane, etc.)	Risk, potential severity of action, timeliness of action (e.g., is travel history relevant); Prioritization and triaging
Vital Signs	The patient's relevant vital signs.	Indication of possible severity of condition
Therapeutic Medication Response	The therapeutic response to a medication (as opposed to an undesired reaction). e.g., Positive response to naloxone administration after a suspected naloxone administration.	Confirmatory response can be indicative of suspected condition.
Homeless	The patient's homeless status.	Risk indicator; important health equity indicator
Immunization Status	The patient's current immunization status and pertinent immunization history.	Risk, potential severity of action, timeliness of action
Vaccine Credential Patient Assertion	Whether or not the patient has asserted that they have verifiable vaccine credentials.	Indicator of vaccine history
Gender Identity	The patient's gender identity. (Different from patient gender (administrativeGender) and birth sex).	Demographic reporting
Procedure	Interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the encounter.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment

<b>eICR ELEMENT NAME</b>	<b>eICR DESCRIPTION</b>	<b>RATIONALE / JUSTIFICATION</b>
Planned Procedure	Interventional, surgical, diagnostic, or therapeutic procedures or treatments planned as a result of the encounter.	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Disability Status	A set of questions used to measure disability.	Risk indicator; important health equity indicator
Emergency Outbreak Information	Information that is required during a public health emergency/outbreak.	Risk indicator; ability to share critical information with public health associated with an outbreak
Exposure/Contact Information	Potential patient exposure and contact information.	Risk indicator
Tribal Affiliation	The name of a patient's affiliated tribe and whether or not the patient is an enrolled member.	Demographic reporting; important health equity indicator
Country of Nationality	Country of nationality (when patient has recent travel history).	Demographic reporting
Country of Residence	Country of residence (when patient has recent travel history).	Demographic reporting
Reportability Response information	This information does not come from the healthcare organization/EHR.	For PHA internal use only: Information from a Reportability Response that was generated in response to the eICR.

## 6.2 eICR CDA Template Hierarchy

The following diagram shows the hierarchy of the main CDA templates used in the eICR. Note that due to space considerations there are some C-CDA section and entry templates not represented in this diagram. See Volume 2 of the IG for the complete listing of templates.

**Figure 37: eICR Template Hierarchy**



## 6.3 Mapping of Data Elements to CDA R2 Templates

The following table maps data elements to the conformance identifiers used in Volume 2 of the Implementation Guide.

**Figure 38: Data Elements Mapped to CDA**

<b>Data Elements and Select Values</b>	<b>CDA Document/Section</b>	<b>CDA Mapping</b>	<b>CDA Data Type</b>
Date of the Report	US Realm Header (V4)	ClinicalDocument/effectiveTime	TS
Provider ID	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/id  [External encounter case]: ClinicalDocument/author/assignedAuthor/id	II
Provider Name	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/assignedPerson/name  [External encounter case]: ClinicalDocument/author/assignedAuthor/assignedPerson/name	PN
Provider Phone	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/telecom/[tel:]  [External encounter case]: ClinicalDocument/author/assignedAuthor/telecom/[tel:]	TEL
Provider Fax	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/telecom/[fax:]  [External encounter case]: ClinicalDocument/author/assignedAuthor/telecom/[fax:]	TEL
Provider Email	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/telecom/[mailto:]  [External encounter case]: ClinicalDocument/author/assignedAuthor/telecom/[mailto:]	TEL

<b>Data Elements and Select Values</b>	<b>CDA Document/Section</b>	<b>CDA Mapping</b>	<b>CDA Data Type</b>
Provider Address	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/address  [External encounter case]: ClinicalDocument/author/assignedAuthor/address	AD
Provider Facility/Office Name	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/representedOrganization/name	PN
Provider Facility/Office Address	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/representedOrganization/address	AD
Provider Facility/Office Telecom	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/representedOrganization/telecom	TEL
Facility ID	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/id  [External encounter case]: ClinicalDocument/author/assignedAuthor/representedOrganization/id	II
Facility Address	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/location/address	AD
Facility Name	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/location/name	
Facility Type	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/code	CD
Healthcare Organization Contact Name	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/serviceProviderOrganization/name	
Healthcare Organization Contact Phone	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/serviceProviderOrganization/telecom[tel:]	TEL

<b>Data Elements and Select Values</b>	<b>CDA Document/Section</b>	<b>CDA Mapping</b>	<b>CDA Data Type</b>
Healthcare Organization Contact FAX	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/serviceProviderOrganization/telecom[fax:]	TEL
Healthcare Organization Contact Address	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/serviceProviderOrganization/addr  [External encounter case]: ClinicalDocument/author/assignedAuthor/representedOrganization/addr	AD
Encounter Type	US Realm Header (V4)	ClinicalDocument/componentOf/encompassingEncounter/code	CD
Patient ID Number	US Realm Header (V4)	ClinicalDocument/recordTarget/patientRole/id	II
Patient Name	US Realm Header (V4)	ClinicalDocument/recordTarget/patientRole/patient/name	PN
Patient Phone	US Realm Header (V4)	ClinicalDocument/recordTarget/patientRole/telecom[tel:]	TEL
Patient Email	US Realm Header (V4)	ClinicalDocument/recordTarget/patientRole/telecom[mailto:]	TEL
Parent/Guardian Name	US Realm Header (V4)	Clinical Document/record target/patientRole/patient/guardian/guradianPerson/name	PN
Parent/Guardian Phone	US Realm Header (V4)	Clinical Document/record target/patientRole/patient/guardian/telecom[tel:]	TEL
Parent/Guardian Email	US Realm Header (V4)	Clinical Document/record target/patientRole/patient/guardian/telecom[mailto:]	TEL
Patient Street Address	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/recordTarget/patientRole/addr	AD
Birth Date	US Realm Header (V4)	ClinicalDocument/recordTarget/patientRole/patient/birthTime	
Patient Birth Sex	Social History Section	Birth Sex Observation/value[xsi:type="CD"]	CD
Patient Gender	US Realm Header (V4)	ClinicalDocument/recordTarget/patientRole/patient/gender	CD

<b>Data Elements and Select Values</b>	<b>CDA Document/Section</b>	<b>CDA Mapping</b>	<b>CDA Data Type</b>
Race	US Realm Header (V4)	ClinicalDocument/recordTarget/patientRole/patient/raceCode + ClinicalDocument/recordTarget/patientRole/patient/sdtc:raceCode	CD
Ethnicity	US Realm Header (V4)	ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode + ClinicalDocument/recordTarget/patientRole/patient/sdtc:ethnicGroupCode	CD
Preferred Language	US Realm Header (V4)	ClinicalDocument/recordTarget/patientRole/patient/languageCommunication/languageCode	CD
Current Occupation	Occupational Data for Health Template Requirements Section (V2)	Past or Present Occupation Observation/value[xsi:type="CD"]  (For current occupation, statusCode="active" and effectiveTime/high is omitted.)	CD
Usual Occupation	Occupational Data for Health Template Requirements Section (V2)	Usual Occupation Observation/value[xsi:type="CD"]	CD
Current Industry	Occupational Data for Health Template Requirements Section (V2)	Past or Present Industry Observation/value[xsi:type="CD"]	CD
Usual Industry	Occupational Data for Health Template Requirements Section (V2)	Usual Industry Observation/value[xsi:type="CD"]	CD
Current Job Title	Occupational Data for Health Template Requirements Section (V2)	Past or Present Occupation Observation/text  For current job title, statusCode="active" and effectiveTime/high is omitted.	ST
Current Employer Name	Occupational Data for Health Template Requirements Section (V2)	Past or Present Occupation Observation/participant/participantRole/playingEntity/name  For current employer, statusCode="active" and effectiveTime/high is omitted.	EN

<b>Data Elements and Select Values</b>	<b>CDA Document/Section</b>	<b>CDA Mapping</b>	<b>CDA Data Type</b>
Current Employer Phone	Occupational Data for Health Template Requirements Section (V2)	Past or Present Occupation Observation/participant/participantRole/telecom <sup>17</sup>  For current employer, statusCode ="active" and effectiveTime/high is omitted.	TEL
Current Employer Address	Occupational Data for Health Template Requirements Section (V2)	Past or Present Occupation Observation/participant/participantRole/addr  For current employer, statusCode ="active" and effectiveTime/high is omitted.	AD
Occupational Exposure <sup>18</sup>	Occupational Data for Health Template Requirements Section (V2)	Occupational Hazard Observation/value[xsi:type="ST"]	ST
Employment Status	Occupational Data for Health Template Requirements Section (V2)	History of Employment Status/value	CD
Pregnancy status (yes, no, possible, unknown)	Pregnancy Section	Pregnancy Observation (SUPPLEMENTAL PREGNANCY)/code	CD
Pregnancy status determination method aka Certainty of status (i.e., ultrasound, lab test evidence)	Pregnancy Section	Pregnancy Observation (SUPPLEMENTAL PREGNANCY)/methodCode	CD

<sup>17</sup> The telecom data element is not specifically called out in the Past or Present Occupation Observation, but it is part of the underlying CDA Observation structure.

<sup>18</sup> An Occupational Hazard is a source of potential harm to one's health that may be encountered at work. An Occupational Exposure is a known interaction with an occupational hazard in a way that increases the risk of harm.

<b>Data Elements and Select Values</b>	<b>CDA Document/Section</b>	<b>CDA Mapping</b>	<b>CDA Data Type</b>
Pregnancy status recorded date	Pregnancy Section	Pregnancy Observation (SUPPLEMENTAL PREGNANCY)/author/time/@value	TS
Estimated date of delivery (EDD)	Pregnancy Section	Estimated Date of Delivery (SUPPLEMENTAL PREGNANCY)/value[xsi:type="TS"]	TS
Estimated date of delivery (EDD) method	Pregnancy Section	Estimated Date of Delivery (SUPPLEMENTAL PREGNANCY)/code	CD
Estimated gestational age (expressed in days)	Pregnancy Section	Estimated Gestational Age of Pregnancy/value	PQ
Estimated gestational age determination date	Pregnancy Section	Estimated Gestational Age of Pregnancy/effectiveTime	TS
Estimated gestational age determination method	Pregnancy Section	Estimated Gestational Age of Pregnancy/code	CD
Last menstrual period (LMP)	Pregnancy Section	Last Menstrual Period (V2)/value	TS
Pregnancy outcome	Pregnancy Section	Pregnancy Outcome/value[xsi:type="CD"]	CD
Pregnancy outcome date	Pregnancy Section	Pregnancy Outcome/effectiveTime	TS
Postpartum status	Pregnancy Section	Postpartum Status/value[xsi:type="CD"]	CD
Visit Date/Time (For outpatient encounters)	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/encompassingEncounter/effectiveTime/low	TS
Admission Date/Time	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/encompassingEncounter/effectiveTime/low	TS
Discharge Date/Time	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/encompassingEncounter/effectiveTime/high	TS
History of Present Illness	History of Present Illness Section	History of Present Illness Section/text	ST
Reason for Visit	Reason for Visit Section	Reason for Visit Section/text	ST

<b>Data Elements and Select Values</b>	<b>CDA Document/Section</b>	<b>CDA Mapping</b>	<b>CDA Data Type</b>
Chief Complaint	Chief Complaint Section	Chief Complaint Section/text	ST
Past Medical History	Past Medical History (V2)	Past Medical History (V2)/Problem Observation (V3)/value[xsi:type="CD"] + Past Medical History (V2)/text	CD ST
Review of Systems	Review of Systems Section	Review of Systems Section/text	ST
Date of Onset	Problem Section (entries required) (V3) + Encounters Section (entries optional) (V3)	Problem Observation (V3)/effectiveTime	TS
Symptoms (list)	Problem Section (entries required) (V3) + Encounters Section (entries optional) (V3)	Problem Observation (V3)/value[xsi:type="CD"]	CD
Lab Order Code (Ordered lab test name)	Plan of Treatment Section (V2)	Planned Observation (V2)/code	CD
Lab Order Code (Resulted lab test name)	Results Section (entries required) (V3)	Result Observation (V3)/code	CD
Lab Order Code (Trigger) (Ordered lab test name)	Plan of Treatment Section (V2)	Initial Case Report Trigger Code Lab Test Order/code	CD
Lab Order Code (Trigger) (Resulted lab test name)	Results Section (entries required) (V3)	Initial Case Report Trigger Code Result Observation (V2)/code	CD
Laboratory Result	Results Section (entries required) (V3)	Result Observation (V3)/value[xsi:type="CD"]	CD
Laboratory Result (Trigger)	Results Section (entries required) (V3)	Initial Case Report Trigger Code Result Observation (V2)/value[xsi:type="CD"]	CD
Specimen source	Results Section (entries required) (V3)	Specimen Collection Procedure (ID)/targetSiteCode	CD
Specimen type	Results Section (entries required) (V3)	Specimen Participant (ID)/participantRole/code	CD
Specimen ID	Results Section (entries required) (V3)	Specimen Participant (ID)/participantRole/id	II

<b>Data Elements and Select Values</b>	<b>CDA Document/Section</b>	<b>CDA Mapping</b>	<b>CDA Data Type</b>
Specimen collection date	Results Section (entries required) (V3)	Specimen Collection Procedure (ID)/effectiveTime	TS
Laboratory Result Status	Results Section (entries required) (V3)	Laboratory Result Status (ID)/code	CD
Laboratory Observation Result Status	Results Section (entries required) (V3)	Laboratory Observation Result Status (ID)/code	CD
Filler Order Number	Results Section (entries required) (V3)	Result Organizer (V3)/id + Initial Case Report Trigger Code Result Organizer/id	II
Diagnoses	Encounters Section (entries required) (V3) + Problem Section (entries required) (V3)	Problem Observation (V3)/value[xsi:type="CD"]	CD
Diagnosis (Trigger)	Encounters Section (entries required) (V3) + Problem Section (entries required) (V3)	Initial Case Report Trigger Code Problem Observation/value[xsi:type="CD"]	CD
Date of Diagnosis <sup>19</sup>	Encounters Section (entries required) (V3) + Problem Section (entries required) (V3)	Problem Observation (V3)/effectiveTime	TS
Medications Administered (list)	Medications Administered Section (V2)	Medication Information (V2)/manufacturedMaterial/code	CD
Death Date	Initial Public Health Case Report Document (eICR) (V6)	ClinicalDocument/recordTarget/patientRole/sdtc:deceasedTime	TS
Immunization Status	Immunizations Section (entries required) (V3)	Immunization Medication Information (V2)/manufacturedMaterial/code	CD
Travel History Dates	Social History Section (V3)	Travel History/effectiveTime	TS
Travel History Location - Free Text	Social History Section (V3)	Travel History/text	ST

<sup>19</sup> Date of diagnosis in C-CDA is, at the time of publication, an outstanding issue. The current guidance from the HL7 Structured Documents Work Group is: when Problem Observation/code = "Diagnosis" (29308-4 Diagnosis) or (282291009 Diagnosis interpretation (observable entity) then effectiveTime/low is the date of diagnosis.

<b>Data Elements and Select Values</b>	<b>CDA Document/Section</b>	<b>CDA Mapping</b>	<b>CDA Data Type</b>
Travel History Location - Coded	Social History Section (V3)	Travel History/participant/participantRole/code	CD
Travel History Location - Address	Social History Section (V3)	Travel History/participant/participantRole/addr	AD
Vital Signs	Vital Signs Section (entries required) (V3)	Vital Sign Observation/value	DEFAULT
Therapeutic Response to Medication	Medications Administered Section (V2)	Therapeutic Medication Response Observation/value[xsi:type="CD"]	CD
Homeless	Social History Section (V2)	Characteristics of Home Environment/value="32911000"	CD
Gender Identity	Social History Section (V2)	Gender Identity Observation/value	CD
Procedure	Procedures Section (entries required) (V2)	Procedure Activity Act (V2)/code Procedure Activity Observation (V2)/code Procedure Activity Procedure (V2)/code	CD
Procedure (Trigger)	Procedures Section (entries required) (V2)	Initial Case Report Trigger Code Procedure Activity Act/code Initial Case Report Trigger Code Procedure Activity Observation/code Initial Case Report Trigger Code Procedure Activity Procedure/code	CD
Planned Procedure	Plan of Treatment Section (V2)	Planned Act (V2)/code Planned Observation (V2)/code Planned Procedure (V2)/code	CD
Planned Procedure (Trigger)	Plan of Treatment Section (V2)	Initial Case Report Trigger Code Planned Act/code Initial Case Report Trigger Code Planned Observation/code Initial Case Report Trigger Code Planned Procedure/code	CD
Disability Status	Social History Section (V2)	Disability Status Observation/value	CD

<b>Data Elements and Select Values</b>	<b>CDA Document/Section</b>	<b>CDA Mapping</b>	<b>CDA Data Type</b>
Emergency Outbreak Information	Emergency Outbreak Information Section	Emergency Outbreak Information Observation	Multiple
Exposure/Contact Information	Social History Section (V2)	Exposure/Contact Information Observation	Multiple
Purpose of Travel	Social History Section (V2)	Travel History (V2)/Purpose of Travel Observation/value	CD
Transportation Details	Social History Section (V2)	Travel History (V2)/Transportation Details Organizer/Transportation Details Observation	Multiple
Tribal Affiliation	Social History Section (V2)	Tribal Affiliation Observation	Multiple
Vaccine Credential Patient Assertion	Social History Section (V2)	Vaccine Credential Patient Assertion/value	CD
Country of Nationality	Social History Section (V2)	Country of Nationality Observation/value	CD
Country of Residence	Social History Section (V2)	Country of Residence Observation/value	CD
Reportability Response Relevant Reportable Condition	Reportability Response Information Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/value	CD
Reportability Response Determination of Reportability	Reportability Response Information Section	Reportability Information Organizer/Determination of Reportability/value	CD
Reportability Response Determination of Reportability Reason	Reportability Response Information Section	Determination of Reportability/Determination of Reportability Reason	CD
Reportability Response Determination of Reportability Rule	Reportability Response Information Section	Determination of Reportability/Determination of Reportability Rule	CD

## APPENDIX A — ACRONYMS AND ABBREVIATIONS

AIMS	APHL Informatics Messaging Services
ANSI	American National Standards Institute
APHL	Association of Public Health Laboratories
API	application program interface
ASKU	asked, but not known
ASTHO	Association of State and Territorial Health Officials
CCD	Continuity of Care Document
C-CDA R2.1 CG	C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 1
C-CDA R2.1	Consolidated CDA Templates for Clinical Notes, DSTU 2.1
CDA R2	Clinical Document Architecture, Release 2
CDC	Centers for Disease Control and Prevention
CDS	clinical decision support
CPT	Current Procedural Terminology
CQL	Clinical Quality Language
CSELS	Center for Surveillance, Epidemiology, and Laboratory Services
CSTE	Council of State and Territorial Epidemiologists
DAM	Domain Analysis Model
DRIV	is derived from
DSTU	Draft Standard for Trial Use
eCR	electronic case reporting
EHR	electronic health record
eICR IG	Public Health Case Report, Release 2 - the Electronic Initial Case Report
eICR	electronic initial case report
ELR	electronic laboratory report
EMR	electronic medical record
eRSD	electronic Reporting and Surveillance Distribution
ESP	Electronic Support for Public Health
EVN	event
FHIR	Fast Healthcare Interoperability Resources
HIE	Health Information Exchange
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven

ICD	International Classification of Diseases
ICP	infection control professional
IG	implementation guide
IHE	Integrating the Healthcare Enterprise
ISO	International Standards Organization
IT	information technology
LMP	last menstrual period
LOINC	Logical Observation Identifiers Names and Codes
MIME	Multipurpose Internet Mail Extensions
MSK	information not provided by sender
NA	not applicable
NASK	not asked
NCD	Notifiable Condition Detector
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
NCHS	National Center for Health Statistics
NHCS	National Health Care Surveys
NHIS	National Health Interview Survey
NI	no information
NIOSH	National Institute for Occupational Safety and Health
NNDSS	Nationally Notifiable Disease Surveillance System
NPI	National Provider Identifier
NUBC	National Uniform Billing Committee
NUCC	National Uniform Claim Committee
ODH	Occupational Data for Health
OID	object identifier
ONC	Office of National Coordinator for Health IT
OTH	not an element in the value domain
PH	public health
PHA	public health agency
PHCP	Public Health Community Platform
PHRI	Public Health Case Reporting Initiative
PRN	<i>pro re nata</i> (when necessary)
QID	<i>quater in die</i> (four times per day)

QRDA	Quality Reporting Document Architecture
RCKMS	Reportable Conditions Knowledge Management System
RCTC	reportable condition trigger code
RFC	request for comment
RFD	Retrieve Form for Data Capture
RhIG	Rh Immune Globulin
RHIO	Regional Health Information Organization
RIM	Reference Information Model
RMIM	Refined Message Information Model
RQO	request
S&I	Standards and Interoperability
SDC	Structured Data Capture
sdtc	Structured Documents Technical Committee (namespace identifier)
SDWG	HL7 Structured Documents Working Group
SMART	Substitutable Medical Applications, Reusable Technologies
SNOMED CT	Systemized Nomenclature for Medicine – Clinical Terms
SSN	Social Security Number
STU	Standard for Trial Use
UCUM	Unified Code for Units of Measure
UNK	unknown
URL	uniform resource locator
URN	uniform resource name
USCDI	U.S. Core Data for Interoperability
VIS	Vaccine Information Statement
XML	eXtensible Markup language
XPath	XML Path Language

## APPENDIX B — HIGH LEVEL CHANGE LOG

### Current Release

The following sections give a high-level overview of the changes between the STU release of the *HL7 CDA® R2 Implementation Guide: Public Health Case Report – the Electronic Initial Case Report (eICR) Edition 4 - US Realm* and the previous errata release *Public Health Case Report, Release 2 - the Electronic Initial Case Report (eICR), STU Release 3.1.1 - US Realm*.

### Volume 1 Summary of Changes

- IG Version number changes, publication date changes, filename changes were made throughout the document, but these changes will not be detailed.
- Added Section [Relevant Time Period for Retrieving Data](#)

### Volume 2 Summary of Changes

- Document-Level Templates
  - Initial Public Health Case Report Document (eICR) was versioned to V6 and based on C-CDA US Realm Header (V4)
- Entry-Level Templates
  - Two new entry-level templates were added:
    - Initial Case Report Susceptibility Organism Participant
    - Initial Case Report Susceptibility Result Organizer
  - Four entry-level templates were updated:
    - Initial Case Report Initiation Reason Observation (V3)
    - Initial Case Report Trigger Code Problem Observation (V4)
    - Initial Case Report Trigger Code Result Observation (V3)
    - Initial Case Report Trigger Code Result Organizer (V3)
  - Six entry-level templates (Procedures) were retired:
    - Initial Case Report Trigger Code Planned Act
    - Initial Case Report Trigger Code Planned Observation
    - Initial Case Report Trigger Code Planned Procedure
    - Initial Case Report Trigger Code Procedure Activity Act
    - Initial Case Report Trigger Code Procedure Activity Observation
    - Initial Case Report Trigger Code Procedure Activity Procedure

### Previous Release

The following sections give a high-level overview of the changes between the errata release of the *Public Health Case Report, Release 2 - the Electronic Initial Case Report (eICR), STU Release*

3.1.1 - US Realm and the previous STU release *Public Health Case Report, Release 2 - the Electronic Initial Case Report (eICR)*, STU Release 3.1 - US Realm.

The updates are based on the following Jira issue: <https://jira.hl7.org/browse/CDA-21155>

## **Volume 1 Summary of Changes**

- IG Version number changes, publication date changes, filename changes were made throughout the document, but these changes will not be detailed.

## **Volume 2 Summary of Changes**

- Document-Level Templates
  - Initial Public Health Case Report Document (eICR): Guidance/mapping notes were updated.

## **Previous Release**

The following sections give a high-level overview of the changes between the STU update release of the *Public Health Case Report, Release 2 - the Electronic Initial Case Report (eICR)*, STU Release 3.1 - US Realm and the previous STU release *Public Health Case Report, Release 2 - the Electronic Initial Case Report (eICR)*, STU Release 3.0 - US Realm. For a detailed template change log, see Section 8, Changes from Previous Version, in Volume 2 of this Implementation Guide. The updates are based on the Jira issues here:

[https://jira.hl7.org/issues/?iq1=cf%5B11402%5D%20%3D%20202205\\_Update\\_eICR](https://jira.hl7.org/issues/?iq1=cf%5B11402%5D%20%3D%20202205_Update_eICR)

## **Volume 1 Summary of Changes**

- Typo corrections, non-substantive wording changes were made throughout the document, but these changes will not be detailed.
- Changes to address the following two issues:
  - Update language in the IG to assure that reportable condition decision rules are applied at the healthcare organization or in an intermediary before sending an eICR to a public health agency. This will address the risk of sending eICRs that are not reportable (<https://jira.hl7.org/browse/CDA-20423>).
  - Update implementation guide (including in examples) to remove any mentions of proprietary infrastructure / system names. (<https://jira.hl7.org/browse/CDA-20421>)

## **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 V5:
    - Added containment for C-CDA R2.1 Chief Complaint Section
    - Added containment for C-CDA R2.1 Review of Systems Section
    - Added containment for C-CDA R2.1 Past Medical History (V3)
    - Added containment for C-CDA R2.1 Discharge Diagnosis Section (V3)

- Added containment for C-CDA R2.1 Procedures Section (V2)
  - Added containment for C-CDA R2.1 Admission Diagnosis Section (V3)
  - Added containment for Emergency Outbreak Information Section
  - Added containment for Reportability Response Information Section
- Section-Level Templates
  - No new sections were added.
- Entry-Level Templates
  - Four entry-level templates were updated:
    - Initial Case Report Trigger Code Result Organizer (V2)
    - [C-CDA Companion Guide] Gender Identity Observation (V3)
    - Purpose of Travel Observation (V2)
    - Travel History (V3)
  - One reused entry-level templates were added:
    - [ODH] History of Employment Status
- Value Sets
  - One value set was updated:
    - Travel Purpose

## Previous Release

The following sections give a high-level overview of the changes between the STU release of the *Public Health Case Report, Release 2 - the Electronic Initial Case Report (eICR), STU Release 3.0 - US Realm* and the previous STU release *Public Health Case Report, Release 2 - the Electronic Initial Case Report (eICR), STU Release 2.0 - 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.
  - Updated chapters/sections:
    - 1.1 Purpose
    - 1.6 Current Project
- 0
- Previous Releases
  - 2 Use Case for eICR
  - 5.2 Automatically Initiated eICR Documents
  - Appendix B —High Level Change Log

## 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 V4:
    - Added containment for C-CDA R2.1 Chief Complaint Section
    - Added containment for C-CDA R2.1 Review of Systems Section
    - Added containment for C-CDA R2.1 Past Medical History (V3)
    - Added containment for C-CDA R2.1 Discharge Diagnosis Section (V3)
    - Added containment for C-CDA R2.1 Procedures Section (V2)
    - Added containment for C-CDA R2.1 Admission Diagnosis Section (V3)
    - Added containment for Emergency Outbreak Information Section
    - Added containment for Reportability Response Information Section
- Section-Level Templates
  - Two new sections were added:
    - Emergency Outbreak Information Section
  - Seven reused section-level templates were added:
    - C-CDA R2.1 Chief Complaint Section
    - C-CDA R2.1 Review of Systems Section
    - C-CDA R2.1 Past Medical History (V3)
    - C-CDA R2.1 Discharge Diagnosis Section (V3)
    - C-CDA R2.1 Procedures Section (V2)
    - C-CDA R2.1 Admission Diagnosis Section (V3)
    - RR: Reportability Response Information Section
- Entry-Level Templates
  - Two entry-level templates were updated:
    - Initial Case Report Trigger Code Problem Observation (V3)
    - Travel History (V2)
  - Sixteen new entry-level templates were added:
    - C-CDA R2.1 Based: Initial Case Report Trigger Code Planned Act
    - C-CDA R2.1 Based: Initial Case Report Trigger Code Planned Observation
    - C-CDA R2.1 Based: Initial Case Report Trigger Code Planned Procedure
    - C-CDA R2.1 Based: Initial Case Report Trigger Code Procedure Activity Act
    - C-CDA R2.1 Based: Initial Case Report Trigger Code Procedure Activity Observation

- C-CDA R2.1 Based: Initial Case Report Trigger Code Procedure Activity Procedure
- Disability Status Observation
- Emergency Outbreak Information Observation
- Exposure/Contact Information Observation
- Purpose of Travel Observation
- Transportation Details Observation
- Transportation Details Organizer
- Tribal Affiliation Observation
- Vaccine Credential Patient Assertion
- Country of Nationality
- Country of Residence
- Animal Participant
- Location Participant
- Person Participant
- Nine reused entry-level templates were added:
  - RR: Reportability Response Coded Information Organizer
  - RR: Relevant Reportable Condition Observation
  - RR: Reportability Information Organizer
  - RR: Determination of Reportability
  - RR: Routing Entity
  - RR: Responsible Agency
  - RR: Rules Authoring Agency
  - RR: Determination of Reportability Reason
  - RR: Determination of Reportability Rule
- Value Sets
  - Seven value sets were added:
    - Animal
    - Determination of Reportability (eCR)
    - Disability Status
    - Location Relevance (eCR)
    - No Immunization Reason
    - Travel Purpose
    - TribalEntityUS

## Previous Release

The following sections give a high-level overview of the changes between the STU release of the *Public Health Case Report, Release 2 - the Electronic Initial Case Report (eICR), STU Release 2.0 - US Realm* and the previous STU release *Public Health Case Report, Release 2 - the Electronic Initial Case Report (eICR), STU Release 1.1 - 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):
    - 1.9 U.S. Core Data for Interoperability (USCDI) Alignment
    - 5.7 Alternate Initiation of eICR Documents
    - 5.10 Value Set Guidance
  - Updated chapters/sections:
    - 1.1 Purpose
    - 1.2 Audience
    - 1.4 Background
    - 1.5 Scope of the Implementation Guide
    - 1.6 Current Project
- 0
- Previous Releases
  - 1.8 Stakeholders
  - 1.10 Future Work / Relationships to Other Projects / Standards
  - 2 Use Case for eICR
  - 5.4 Trigger Code Templates
  - 5.7 Alternate Initiation of eICR Documents
  - Appendix B —High Level Change Log

### 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 V3:
    - Added containment for Pregnancy Section
    - Added containment for Occupational Data For Health Template Requirements Section
    - Added constraint for setId
    - Added constraint for versionNumber

- Added constraints for relatedDocument
  - Added code for forced reporting
  - Added value set for county
  - Updated examples
- Section-Level Templates
  - Three reused section-level templates were added:
    - C-CDA R2.1 Supplemental ODH: Occupational Data for Health Template Requirements Section
    - C-CDA R2.1 Supplemental: Pregnancy Section
    - C-CDA R2.1: Vital Signs Section (entries required) (V3)
- Entry-Level Templates
  - Four entry-level templates were updated:
    - Initial Case Report Manual Initiation Reason Observation (V2)
    - Initial Case Report Trigger Code Lab Test Order (V2)
    - Initial Case Report Trigger Code Problem Observation (V2)
    - Initial Case Report Trigger Code Result Observation (V2)
  - Four new entry-level templates were added:
    - C-CDA R2.1 Based: Initial Case Report Trigger Code Immunization Information
    - C-CDA R2.1 Based: Initial Case Report Trigger Code Result Organizer
    - C-CDA R2.1 Based: Initial Case Report Trigger Code Medication Information
    - Therapeutic Medication Response Observation
  - Twenty one reused entry-level templates were added:
    - C-CDA R2.1: Characteristics of Home Environment
    - C-CDA R2.1 Supplemental: Estimated Date of Delivery (SUPPLEMENTAL PREGNANCY)
    - C-CDA R2.1 Supplemental: Estimated Gestational Age of Pregnancy
    - NCHS: Gender Identity Observation
    - C-CDA R2.1 Supplemental: Laboratory Observation Result Status (ID)
    - C-CDA R2.1 Supplemental: Laboratory Result Status (ID)
    - C-CDA R2.1 Supplemental: Last Menstrual Period (V2)
    - C-CDA R2.1 Supplemental ODH: Occupational Hazard Observation
    - C-CDA R2.1 Supplemental ODH: Past or Present Industry Observation
    - C-CDA R2.1 Supplemental ODH: Past or Present Occupation Observation

- C-CDA R2.1 Supplemental: Postpartum Status
- C-CDA R2.1 Supplemental: Pregnancy Observation (SUPPLEMENTAL PREGNANCY)
- C-CDA R2.1 Supplemental: Pregnancy Outcome
- C-CDA R2.1 Supplemental: Specimen Collection Procedure (ID)
- C-CDA R2.1 Supplemental: Specimen Condition Observation (ID)
- C-CDA R2.1 Supplemental: Specimen Observation (ID)
- C-CDA R2.1 Supplemental: Specimen Participant (ID)
- C-CDA R2.1 Supplemental: Specimen Reject Reason (ID)
- C-CDA R2.1 Supplemental ODH: Usual Industry Observation
- C-CDA R2.1 Supplemental ODH: Usual Occupation Observation
- C-CDA R2.1: Vital Signs Observation (V2)
- C-CDA R2.1: Vital Signs Organizer (V3)
- Value Sets
  - Two new value sets were added:
    - eICR Initiation
    - PHVS\_County\_FIPS\_6-4

## Previous Release

The following sections give a high-level overview of the changes between the 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 C-CDA Reuse and Conformance

Where C-CDA templates have been reused and not further constrained in this guide there are several cases where the C-CDA containment constraints templates use the **MAY** conformance verb. For example, C-CDA states that the Encounter Activity (V3) **MAY** contain an Encounter Diagnosis (V3). For the purpose of this implementation guide, a select set of these conformance verbs are to be interpreted as **SHOULDs**, i.e. *if the data is available it must be included*. The following is a table of the selected C-CDA containments:

**Figure 30: “SHOULD” eICR Conformance for Selected C-CDA Containments**

Containing C-CDA Template	Contained C-CDA Template	Conformance Number
Encounter Activity (V3)	Encounter Diagnosis	1198-15492
Medications Administered Section (V2)	Medication Activity	1098-8153
Past Medical History (V3)	Problem Observation (V3)	1198-8791
Plan of Treatment Section (V2)	Planned Act (V2)	1098-30473
Plan of Treatment Section (V2)	Planned Immunization Activity	1098-32354
Plan of Treatment Section (V2)	Planned Medication Activity (V2)	1098-8811
Plan of Treatment Section (V2)	Planned Observation (V2)	1098-7726
Plan of Treatment Section (V2)	Planned Procedure (V2)	1098-30474
Pregnancy Section	Last Menstrual Period (V2)	3368-26531
Pregnancy Section	Postpartum Status	3368-26623
Social History Section (V2)	Characteristics of Home Environment	1198-28826
Social History Section (V2)	Pregnancy Observation	1198-9132
Social History Section (V2)	Social History Observation (V3)	1198-7953

- Stand-Alone Templates
- 5.4 Trigger Code Templates
- Appendix A — Acronyms and Abbreviations
- Appendix B — High Level Change Log
- 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 Implementation Guide 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](#).

**Table 4: Extensions Used in this Guide**

Extension	Definition/Usage
sdtc:raceCode	The raceCode extension allows for multiple races to be reported for the recordTarget. <ul style="list-style-type: none"><li>recordTarget/patientRole/patient</li><li>Cardinality: [0..*]</li></ul>
sdtc:ethnicGroupCode	The ethnicGroupCode extension allows for additional ethnicity groups to be reported for the recordTarget. <ul style="list-style-type: none"><li>recordTarget/patientRole/patient</li><li>Cardinality: [0..*]</li></ul>
sdtc:deceasedInd	The deceasedInd extension (= “true” or “false”) is used to record that the recordTarget is deceased. <ul style="list-style-type: none"><li>recordTarget/patientRole/patient</li><li>Cardinality: [0..1]</li></ul>
sdtc:deceasedTime	The deceasedTime extension is used to record the date and time of death of the recordTarget. <ul style="list-style-type: none"><li>recordTarget/patientRole/patient</li><li>Cardinality: [0..1]</li></ul>
sdtc:dischargeDispositionCode	The dischargeDispositionCode extension allows the provider to record a discharge disposition in an encounter activity. <ul style="list-style-type: none"><li>encounter</li><li>Cardinality: [0..1]</li></ul>
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 <a href="#">HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1</a> . <ul style="list-style-type: none"><li>authenticator</li><li>legalAuthenticator</li><li>Cardinality: [0..1]</li></ul>

Extension	Definition/Usage
<code>sdtc:valueSet</code>	<p>The <code>valueSet</code> extension allows the implementer to reference a particular value set from which a code was drawn.</p> <ul style="list-style-type: none"> <li>• CD data type</li> <li>• Cardinality: [0..1]</li> </ul>
<code>sdtc:valueSetVersion</code>	<p>The <code>valueSetVersion</code> extension allows the implementer to reference a specific version of a value set.</p> <ul style="list-style-type: none"> <li>• CD data type</li> <li>• Cardinality: [0..1]</li> </ul>

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.