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

Standard for Trial Use
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Volume 1 – Introductory Material

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  - 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)
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1. Introduction

1.1 Purpose

The purpose of this implementation guide (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 using Consolidated CDA (C-CDA) DSTU Release 2.1 templates to build the eICR document. The submission of public health case reports for specific infectious and non-infectious conditions is required by law in all States and Territories in the United States. In addition to supporting critical public health functions in State, Local, and Territorial Public Health Agencies (PHAs), the data from these case reports will also indirectly support notifications between PHAs and to the Centers for Disease Control and Prevention (CDC) for the Nationally Notifiable Disease Surveillance System (NNDSS) and nationwide disease monitoring.

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

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

In some circumstances the eICR will be all that is needed to support public health reporting. Having electronic case reports on reportable condition sent from EHRs and received by PHAs will represent a significant accomplishment of interoperability between healthcare and public

health. The eICR may lead to the reporting of additional data or follow-up by the PHA to confirm reportability, provide condition-specific or public health jurisdiction-specific case data, and/or support public health investigation, contact tracing, and/or countermeasure administration.

The eICR itself may be conveyed or referenced by a number of different transport methods. It will serve as input to reportability evaluation, including that performed by public health decision support systems, such as the CSTE/CDC Reportable Conditions Knowledge Management System (RCKMS[1]) and others. The ONC Structured Data Capture (SDC) initiative standard may be a good complement to the eICR for the purpose of manually capturing supplemental disease-specific data that may not be available in the EHR into forms. While out of scope for this IG, receiving an eICR will also allow PHAs to communicate the reportability of a condition, along with other relevant public health information, back to clinical care personnel.

1.2 Audience

This IG is designed to provide EHR vendors with the specifications for developing the functionality of EHRs used in hospitals and by ambulatory care providers to report potential cases of reportable conditions to PHAs. This IG is designed to provide public health surveillance systems developers the specifications for implementing functionality used by PHAs to receive, process, and store or archive the eICRs. The IG will also be informative to health care providers, public health staff, analysts, and health information exchange organizations among others. Users of this IG must be familiar with the details of the HL7 CDA R2 document construction and the C-CDA templates.

1.3 Background

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

While case reporting from clinical care to Public Health Agencies is considered to be a core public health function, its electronic implementation has been slow to advance nationally because of a number of challenges. Laws requiring the reporting of infectious and non-

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

infectious conditions are written individually by each public health jurisdiction. Geographic differences in condition prevalence and other jurisdictional variations have created a complex array of reporting expectations making it difficult for providers to know when, where, and what to report. Healthcare providers, for their part, have been historically inconsistent in reporting from clinical care by any process. For example, a recent CDC study indicated that of the cases of Lyme disease recorded as a clinical diagnosis in clinical care, only about one out of ten are reported to the appropriate PHA. [2]

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

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

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

This eICR IG builds on experience, specifications and lessons learned from the HL7 Implementation Guide for CDA Release 2: Public Health Case Reporting Release 1; The ONC S&I Framework Public Health Case Reporting Initiative (PHRI); the Council of State and Territorial Epidemiologists (CSTE) “Minimum EHR Data for an Electronic Initial Case Report (eICR)”; work done by CSTE and CDC on the Reportable Conditions Knowledge Management System (RCKMS); and the Association of State and Territorial Health Officials (ASTHO), Association of Public Health Laboratories (APHL), and the CDC work on trigger codes for reportable conditions as part of the Public Health Community Platform (PHCP).[3]

1.4 Scope of the Implementation Guide

The following areas are In Scope for this IG:

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

[3] www.thephcp.org

- 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 full requirements to generate reports from EHR systems (in all clinical settings where EHR data is used for reporting purposes, e.g., inpatient, outpatient, emergency room, urgent care) to public health agencies (Note: reports may include administrative, laboratory, pharmacy and/or other information imported from separate systems into the EHR).

The following areas are Out of Scope for this IG:

- The definition, specification, format, and vocabularies used, and specific examples or instances of trigger codes used to initiate the sending of an eICR;
- The specifications for supplemental data associated with a report of a reportable condition;
- The specific methods for providers to transmit eICRs to Public Health Agencies (PHAs). Some of these are described in this IG for context purposes only;
- The methods for PHAs to receive and process eICRs;
- The specification and methods for sending a "notice of reportability" or other information from the PHA to clinical care;
- The specifications for PHAs to notify the Centers for Disease Control and Prevention of nationally notifiable diseases;
- The definition of specifications and guidelines on reportable event criteria (e.g., defining reportable conditions) – this implementation guide will enable healthcare providers to submit an initial case report, but will not define all the reporting criteria or all potential elements that a jurisdiction may want in a complete report;

- The definition of automated 'business rules' to identify potential reportable events – this implementation guide will enable healthcare providers to submit a report but will not describe the criteria or business rules to identify when such an eICR should be sent;
- The description of the process for healthcare providers to add information into an EHR or auxiliary system;
- The description of the process for public health agencies to perform follow-up activities, including case monitoring;
- The definition of specifications and guidelines for reporting by means other than the transmission of an electronic message or document (e.g., telephone voice, manual web-entry and mailed or faxed information);
- The description of any additional or extensive bi-directional communication between a PHA and a healthcare provider beyond the sending of an eICR;
- The identification of security requirements, methodologies, procedures, and/or protocols; and
- The identification of information and data stewardship practices and policies.

1.5 Stakeholders

Table 1. The key stakeholder groups interested in this Use Case are included in the table below.

Stakeholders	Description
Electronic Health Record (EHR) / Electronic Medical Record (EMR)	The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. Source: http://www.himss.org/ASP/topics_ehr.asp. For purposes of this IG, EHR can also be interpreted to refer to applications that some vendors may call an Electronic Medical

	Record (EMR).
Healthcare Provider	Any supplier of a healthcare service, i.e., a person or organization, that furnishes, bills, or is paid for healthcare in the normal course of business. Includes physicians and healthcare provider staff, as well as ancillary healthcare personnel (e.g., laboratory personnel)
Health IT Vendor	A vendor or supplier is a company/consortium that provides health information technology products and/or services, in this case, for supporting health or healthcare.
Intermediary System	System that sits between EHR systems and Public Health Information Systems to facilitate exchange and routing of messages. Examples: - Health Information Exchange (HIE) Organizations (HIEs) - Organizations, including state Designated Entities for Health Information Exchange, as well as other organizations, that manage health information exchange among different corporate entities. Includes Regional Health Information Organizations (RHIOs). - Public Health Community Platform (PHCP) Integration Engine - An application that receives messages from the EHR system and parses, and routes messages to a PHA or public health decision support.
Laboratory	The laboratory is a producer of laboratory test results (filler or, at times, placer of a laboratory order).
Laboratory Information System (LIS)	An application to streamline the management of laboratory processes including data collection, workflow management, and report generation. May provide an automatic interface to laboratory analytical instruments to transfer verified results to nurse stations, chart carts, and remote physician offices. Also referred to as a Laboratory Information Management System.

Public Health Agency (PHA)	For the purposes of this IG, a PHA is a governmental entity at the federal, state, territorial, local or tribal level that is legally entitled to establish public health case reporting requirements and receive case reports.
Public Health Decision Support (PHDS)	For the purposes on this IG, PHDS provides clinicians, staff and public health practitioners with knowledge about reporting cases to public health and information about the condition that has been identified. Examples include the Reportable Conditions Knowledge Management System (RCKMS), the Notifiable Condition Detector (NCD), and Electronic Support for Public Health (ESP).
Public Health System	Jurisdictional information systems that may, among other things, receive public health case reports
Standards Development Organization	An organization that identifies the need for, locates interested parties, and writes specifications that all parties in a particular field of human endeavor can use to their mutual benefit. For the purpose of this document, the field is health or health interoperability and recognition by the American National Standards Institute (ANSI) or the International Standards Organization (ISO) is accepted as evidence that a particular organization is a SDO.

1.6 Future work / Relationships to Other Projects / Standards

Establishing an HL7 CDA R2 standard implementation guide for an eICR that can be used by all jurisdictions and all conditions is a critical step in advancing the electronic implementation of case reporting between EHRs and Public Health Agencies. There are also other parts of the clinical care – public health workflow that need consideration when this has been accomplished.

1. Usage guidance and a specification for the communication of trigger codes, e.g. from public health to a provider's EHR system. The specification will include the metadata for all the data values and other guidance needed for sending initial public health report.

2. The Association of Public Health Laboratories (APHL) working with the Association of State and Territorial Health Officials (ASTHO) and the Council of State and Territorial Epidemiologists (CSTE) have developed a draft list of reportable condition trigger codes that EHR vendors can implement to identify relevant clinical diagnoses,

laboratory results and some orders. This trigger code list will continue to be developed and maintained in an ongoing way outside of HL7.

3. A specification for return communication from the PHA to clinical care, specific to the patient in question, and potentially including information about that condition in that community. In addition to the specifics of the initial case report, such a "notice of reportability" could contain information such as whether the condition is definitively reportable in that jurisdiction, if there are additional data needed to definitively determine reportability, links to the full reporting requirements in that jurisdiction, links to forms for the input of supplemental data desired for that condition, information about who to contact in the PHA if there are issues to work through via other means, and potentially other information, as needed for public health activities.

4. Specifications need to be developed for PHAs to create and communicate computable and interoperable alerts for consumption by EHRs to render to their clinical users. PHA alerting today is typically generalized and may relate to multiple suspicious cases, environmental events, or other important public health information important for clinical care providers. Providing an interoperability standard for communicating these alerts could enable PH alerts viewable by clinical staff from within an EHR, as well as be computable and queryable. This alerting area may be in scope for other public health projects.

5. On receiving an eICR, PHA personnel may use the information contained therein as a basis for further investigation, to seek more information from clinical care or from a health information exchange, and to close the case or otherwise manage the case and the case status. The ONC Structured Data Capture (SDC) initiative standard may be helpful with providing forms for inputting supplemental information, but further domain analysis and implementation guide work may be needed in these areas as well.

6. With the advent of HL7 FHIR, there will be needs to also map data elements to FHIR, to possible develop new FHIR resources, and/or FHIR profiles for the eICR. This work will proceed as part of this project by working from relevant data elements in the CSTE Task Force report and the eICR C-CDA IG.

7. For the complete public health reporting continuum, two additional reporting mechanisms are important for consideration in future related work; reporting between public health jurisdictions or Public Health to Public Health reporting, and Public Health Case Notification.

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

of report or because of the reporting rules within a specific jurisdiction. This is regular process that jurisdictions routinely complete often times in a manual manner. Being able to transfer cases and associated investigation information to the appropriate jurisdiction electronically would help make the reporting process more efficient may provide the necessary information for public health intervention more timely and accurately.

Additionally, for some reportable conditions identified by the CSTE and CDC, there is also the need for Public Health jurisdictions 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 have also been times when different jurisdictions have used varying data elements without a clear basis. 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.

NOTE: The examples and comments in Chapters 2 and 3, are not normative and any conflict between content therein and Chapters 1 or 4 should be favor the specifications in Chapters 1 and 4.

2. Use Case for eICR

The scope of this implementation guide is limited to the generation of an eICR from clinical care. However, eICR generation is only one part of the overall electronic case reporting flow. The broader electronic case reporting flow is depicted in the context use case diagram in section2.1, and also referenced in the assumptions, pre-conditions and post-conditions of this section. The broader electronic case reporting picture is included both to show where eICR fits (the focus for this IG), and to highlight integral components that should be addressed in subsequent IGs or companion guidance to provide adequate support for full eICR implementation.

2.1 Context Use Case Flow Diagram

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

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

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

Likewise, the eICR could be:

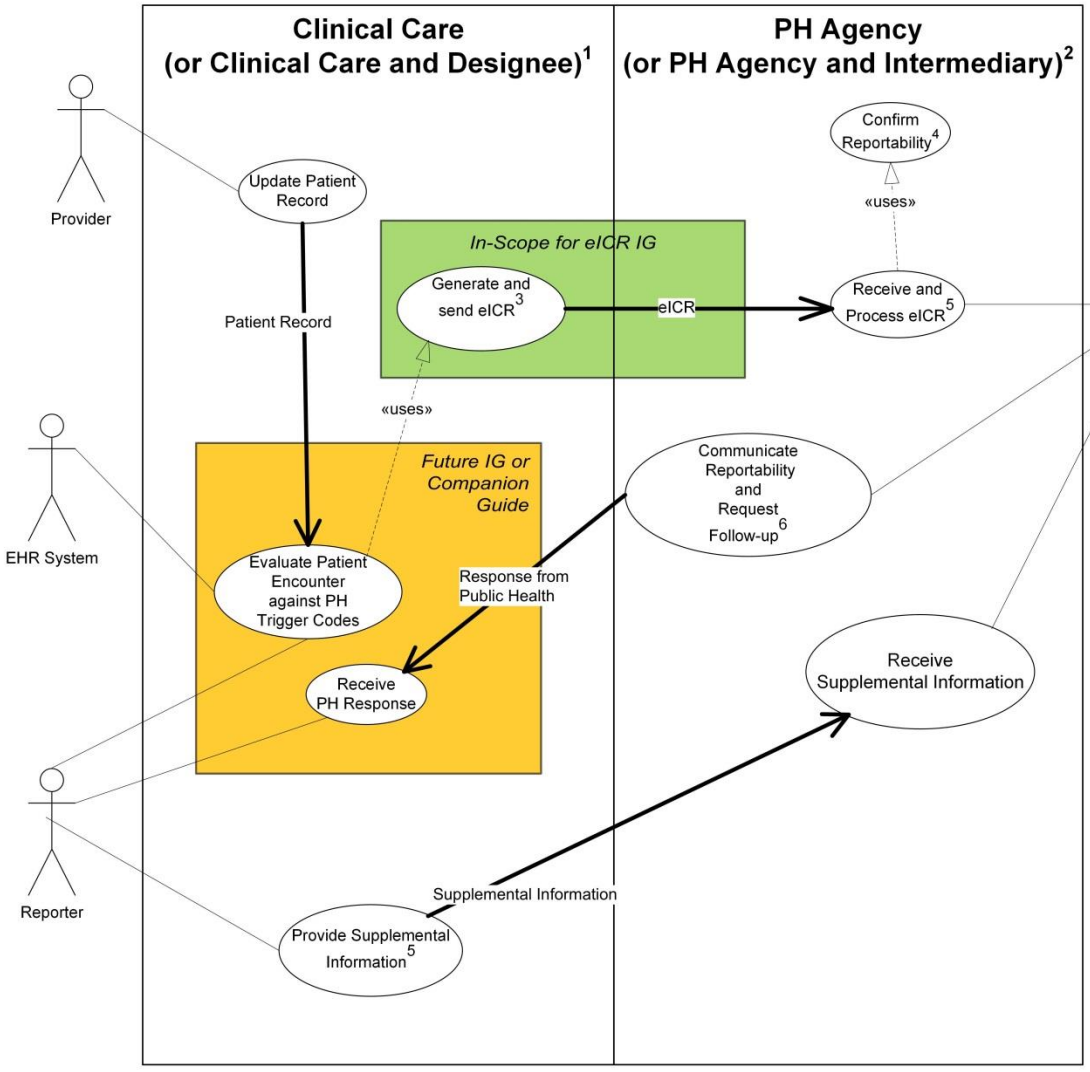
- received directly by the PHA; or by an
- intermediary for the PHA, such as the Public Health Community Platform (PHCP) or an HIE,

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

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

- a centralized but jurisdiction specific decision support service such as RCKMS;
- a localized decision support service such as ESP; or
- using manual inspection at a jurisdiction in the absence of an automated approach.

Context Use Case Diagram:
Electronic Case Reporting Use Case to PH Agency



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Legend

Green – in scope for eICR Implementation Guide

Orange – planned for future Implementation Guide or Companion guide

1) Alternate flow could be through HIE or other clinical network
2) Alternate flow could be to Public Health intermediary (e.g., PHCP)
3) Alternate flow could be physician initiation of eICR of a possible reportable condition
4) This refers to public health decision support (e.g., RCKMS, ESP, manual inspection)
5) Could include routing to PHA if PH intermediary is included
6) Possible communications may include:
   - PHA accepts initial case report and sends Notice of Reportability with no follow-up necessary
   - PHA accepts initial case report, sends Notice of Reportability and requests follow-up by:
     - May query an HIE for more information
     - May include request for supplemental data from reporter (e.g., include link to request supplemental data in Notice of Reportability)
     - May request follow-up by phone

2.2 Use Case Assumptions

- Patient-level clinical information is entered, imported, or accessed by a healthcare provider using an EHR system.
- Broadly-acceptable security and transport protocols, patient identification methodology, privacy and security procedures, coding, vocabulary, and normalization standards exist and are in use by the EHR system and PHA system.
- The EHR system contains or has access to all relevant information and data (e.g., demographic, clinical, laboratory, pharmacy) to generate a complete and accurate eICR in accordance with requirements described in this implementation guide.
- Appropriate data and information stewardship practices are adopted by exchange partners.
- Network and policy infrastructure exist to enable consistent, appropriate, and accurate information exchange across exchange partners.
- The EHR system may be a single stand-alone system or based upon a component-based architecture. The EHR may interface with other systems that are used to help create, populate or transmit the report to public health or its intermediary.
- The PHA system and/or its intermediary system is in place, is capable of receiving and consuming the report, and receives the report in a standardized structured format.
    - These information systems may be a single stand-alone system or be component based systems used to receive, process, store or archive, as appropriate, the report for review and/or analysis.
- For automated reporting, there is a common standard set of codes used to automatically match against (i.e., trigger codes) information in a patient encounter to initiate the creation and sending of an eICR from all EHR systems. Initial electronic case report documents can also be manually initiated.
- There is a standard structure and set of data elements for the eICR, defined by this IG, that is accepted by all jurisdictions, for all conditions.
- The EHR system is capable of sending the eICR to a PHA system or its intermediary system.
- Confirmation of Reportability will be done by public health decision support outside of the EHR/clinical care system.

    - Public Health (PH) decision support can, at times, handle the variation in requirements for reporting that exist across local, state, tribal, and territorial boundaries.

- The intermediary system HIE, if used, is responsible for passing the acknowledgement from the Public Health Agency Information system to the EHR system; the intermediary system may send separate acknowledgements, but these are not considered the authoritative acknowledgement.

2.3 Pre-Conditions

The following have occurred:

- An authoritative set of trigger codes, as provided and defined by PH, is maintained and used within the EHR system.
- The creation of an eICR is initiated by one of two methods:
    - An automated match of information in a patient record for an encounter to a set of trigger codes within the EHR; or
    - Manual initiation of the creation of an electronic report to public health by a provider.
- The 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).
- The EHR system populates/generates a report using all appropriate information (e.g., data elements and terminology) for the eICR.

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 eCIR sent from the EHR to the public health agency is stored in a log within the authoring system at the EHR.
- A record of receipt of the eICR is recorded in a log, in the PHA system and/or its intermediary system.

2.5 Actors and Roles

Table 2. The actors and a description of their roles are included in the table below.

Actor	Role
Provider	• A person in clinical care organization that updates information in the EHR System
EHR System (healthcare provider system)	• Collect, receive, and/or store data on a patient record • Consume and maintain trigger codes • Match trigger code and generate eICR • Create report and transport to intermediary system or appropriate PHA
Reporter	• A person in clinical care organization that is responsible for reporting to public health
Public Health Agency System	• Receive report from EHR system or intermediary
PH Jurisdiction User	• The person in a public health agency that uses the information contained in the PHA system

Clinical Care (or Clinical Care and Designee)	• Implementer and user or EHR System; or • As designee of clinical care (e.g., HIEs): ○ Receive eICR from EHR system and send to Intermediary or PHA system
Public Health Agency (or PHA and Intermediary)	• Recipient of eICR from EHR system or clinical care designee • Confirmer of reportability • And if at PH intermediary, sender of eICR to PHA system

2.6 Scenarios for Reporting an eICR to Public Health

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

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

The eICR is received by one or more appropriate PHAs the eICR is evaluated using public health decision support and a notice of reportability is returned to the sending EHR system, inclusive of the public health decision support results. The notice of reportability includes the confirmation of reportability, information about the responsible public health jurisdiction, and over time, a request for supplemental information about the event if needed and/or information about the status of disease in the community.

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

Narrative with example:

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

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

Alternative – Public Health Intermediary

The PHA may employ a intermediary's decision support tool to receive the eICR and confirm it's reportability. This intermediary would confirm 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 to. Pertinent information includes patient address and facility location to determine the jurisdiction with authority to receive this information. The PHA determines whether or not an intermediary will be used.

Narrative with Public Health Intermediary

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

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

The intermediary receives the eICR from the EHR system, evaluates the document against centrally hosted public health decision logic to determine the potential public health reportability based on the facility, provider, and/or patient address and patient encounter characteristics. The intermediary will route the eICR to the correct PHA consistent with the results of the public health decision support.

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

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

Alternative - Manually initiated eICRs

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

3. Data Requirements and IG Template Specifications Organization

The CDA templates expressed in this specification are grouped according to type: Document, Section, Entry, and Datatype. Templates are arranged alphabetically within type. Each

template is presented with a template title followed by template type and object identifier (OID), and a table of hyperlinked nested and encompassing templates.

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

a. This assignedEntity SHALL contain at least one [1..*] id (CONF:2218-8). Note: ResponsibleProvider.identifier

The templates used in this guide are a reuse 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. The electronic Initial Public Health Case Report Document (eICR) template is unique to this guide and establishes the document header for the eICR document type. This header extends the C-CDA US Realm Header 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 section templates.

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

3.1 Conventions used in this implementation guide

The conformance verb keyword at the start of a constraint (**SHALL** , **SHOULD** , **MAY**, etc.) indicates usage conformance. **SHALL** is an indication that the constraint is to be enforced without exception; **SHOULD** is an indication that the constraint is optional but highly recommended; and **MAY** is an indication that the constraint is optional and that adherence to the constraint is at the discretion of the document creator.

All templates in the guide have been designated as "Open" templates. The implication is that attributes or attribute properties declared in the CDA Refined Message Information Model (R-MIM) but not in this specification are allowed. The intent behind this convention is to allow the use of null flavor for any and all attributes, attribute properties, and traversals.

The cardinality indicator (0..1, 0..*, 1..1, 1..*, etc.) specifies the allowable occurrences within an instance. Thus, "**MAY** contain 0..1" and "**SHOULD** contain 0..1" both allow for a document to omit the particular component, but the latter is a stronger recommendation that the component be included if it is known.

The following cardinality indicators may be interpreted as follows:

- 0..1 as contains zero or one
- 1..1 as contains exactly one
- 1..* as contains one or more
- 0..* as contains zero or more

Each constraint is uniquely identified by a conformance identifier placed at or near the end of the constraint (e.g., "CONF:2218-107").

3.2 Populating the Public Health Case Report, Release 2 as it relates to the use of Null Values:

The constraint of “SHALL” has been applied to the majority of data elements identified in Section 3.4 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. However, there is a small subset of data elements that the Public Health Agency Information System requires in order to process a case report. This implementation guide uses “SHALL NOT contain 0..0] @nullFlavor” to indicate nullFlavor is not allowed for these elements.

3.2.1

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 (CONF:2218-141)
- Facility Type (CONF:2218-14)
- Visit Date/Time (CONF:2218-5)
- Diagnoses Encounter (CONF:1198-9058)

3.2.2

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 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 fields in C-CDA 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 2: 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).

3.2.3

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 normative edition. Any **SHALL**, **SHOULD** and **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 3: Attribute Required (nullFlavor not allowed)

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

or

2. SHALL contain exactly one [1..1] effectiveTime/@value (CONF:5256).

Figure 4: 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>
```

Figure 5: nullFlavor Not Allowed on Element (with XML example)

1. **SHALL** contain exactly one [1..1] targetSiteCode (CONF:1169-32487)
a. This targetSiteCode **SHALL** contain exactly one [1..1] @code (CONF:1169-32488) b. This targetSiteCode **ab** contain exactly one [1..1] @codeSystem (CONF:1169-33182)

```
<targetSiteCode xsi:type="CD" code="181131000"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
displayName="Entire breast">
```

3.2.4

If a sender wants to state that a piece of information is unknown, this is an example of how an author can record a section that contains “No Information”. This is an exceptional case and does not cover 'No Known' scenarios (see below).

Figure 6: No Information for Problem List

```
<!-- ************************* PROBLEM LIST ***************************** -->
<component>
  <!-- nullFlavor of NI indicates No Information.-->
  <!-- Validator currently checks for entries even in case of nullFlavor - this will need to be
updated if approved.-->
  <section nullFlavor="NI">
    <!-- conforms to Problems section with entries optional -->
    <templateId root="2.16.840.1.113883.10.20.22.2.5.2"/>
    <!-- conforms to Problems section with entries required -->
    <templateId root="2.16.840.1.113883.10.20.22.2.5.1.2"/>
    <code code="11450-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
      displayName="PROBLEM LIST"/>
    <title>PROBLEMS</title>
    <text>No Information</text>
  </section>
</component>
```


3.2.5

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

Previously Continuity of Care Document (CCD), Intergrating the Healthcare Enterprise (IHE), and the Healthcare 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.

3.2.6

The next example illustrates additional nuances of representing information that is a negative assertion, where 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 7: 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>
```

3.3 Use of vocabulary standards

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (SHALL , SHOULD , MAY, etc.) and an indication of DYNAMIC vs. STATIC binding. The use of SHALL requires that the component be valued with a member from the cited value set; however, in every case any HL7 "null" value such as other (OTH) or unknown (UNK) may be used. DYNAMIC binding means that the allowed values bind to the most current version of the value set. STATIC binding means that the allowed values of the value set are bound to a specifc version of a value set. If a STATIC binding is specified, a date SHALL be included to indicate the value set version.

Figure 8: Vocabulary bindings are specified as a reference to the value set name followed by the value set OID; for example: This patient **SHALL** contain exactly one

[1..1] **administrativeGenderCode**, which **SHALL** be selected from ValueSet **Administrative Gender (HL7 V3)** urn:oid:2.16.840.1.113883.1.11.1 **DYNAMIC** (CONF:1198-6394).

Value sets specifications are included in the section entitled "Value Sets In This Guide"(Section 9, Volume 2). Each value set includes a value set member list including the code, code system name, and print name for each member of the value set. The name of the value set, along with its OID is included in the table header.

Example from Volume 2: Table 1: Administrative Gender (HL7 V3)

Value Set: Administrative Gender (HL7 V3) urn:oid:2.16.840.1.113883.1.11.1
Administrative Gender based upon HL7 V3 vocabulary. This value set contains only male, female and undifferentiated concepts.
Value Set Source:
http://www.hl7.org/documentcenter/public/standards/vocabulary/vocabulary_tables/infrastructure/vocabulary/vocabulary.html

Code	Code System	Code System OID	Print Name
F	AdministrativeGender	urn:oid:2.16.840.1.113883.5.1	Female
M	AdministrativeGender	urn:oid:2.16.840.1.113883.5.1	Male
UN	AdministrativeGender	urn:oid:2.16.840.1.113883.5.1	Undifferentiated

3.4 CSTE Identified Data Requirements

Table 3 below contains a set of data element requirements proposed by the CSTE and used to map data for this standard. The following sections contain reference tables and graphics of the data model used in this document.

CSTE ELEMENT NAME	CSTE DESCRIPTION	RATIONALE / JUSTIFICATION
Date of the Report	The date on which the reporting party (e.g., physician, nurse practitioner, physician assistant, etc.), completes collection of minimum data for the eICR	Used to assess timelines of eICR data provisioning, and other quality assurance tasks
Report Submission Date/Time	The date and time at which the EHR system sends the eICR data to the jurisdictional public health agency or designee	Used to ensure timeliness of report and to identify time lags between date of the report and when the EHR sends the report
Sending Application	The name of the sending application	Used to ensure quality and integrity of eICR data
Provider ID	Identification code for the care provider (e.g., NPI)	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.

CSTE ELEMENT NAME	CSTE DESCRIPTION	RATIONALE / JUSTIFICATION
Provider Name	The first and last name of the healthcare provider	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Provider Phone	The provider's phone number with area code	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Provider Fax	The provider's fax number with area code	Necessary to obtain additional info during case follow-up phase or to submit supplemental information
Provider Email	The provider's email address	If secure email is available; used for sharing secure links to health data if allowed by state regulations
Provider Facility/Office Name	The provider facility's full name, not necessarily where care was provided to patient	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Provider Address	The geographical location or mailing address of the provider's office or facility. Address must include street address, office or suite number (if applicable), city or town, state, and zip code	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Facility ID Number	Identification code for the facility (e.g., Facility NPI)	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Facility Name	The facility's name	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.

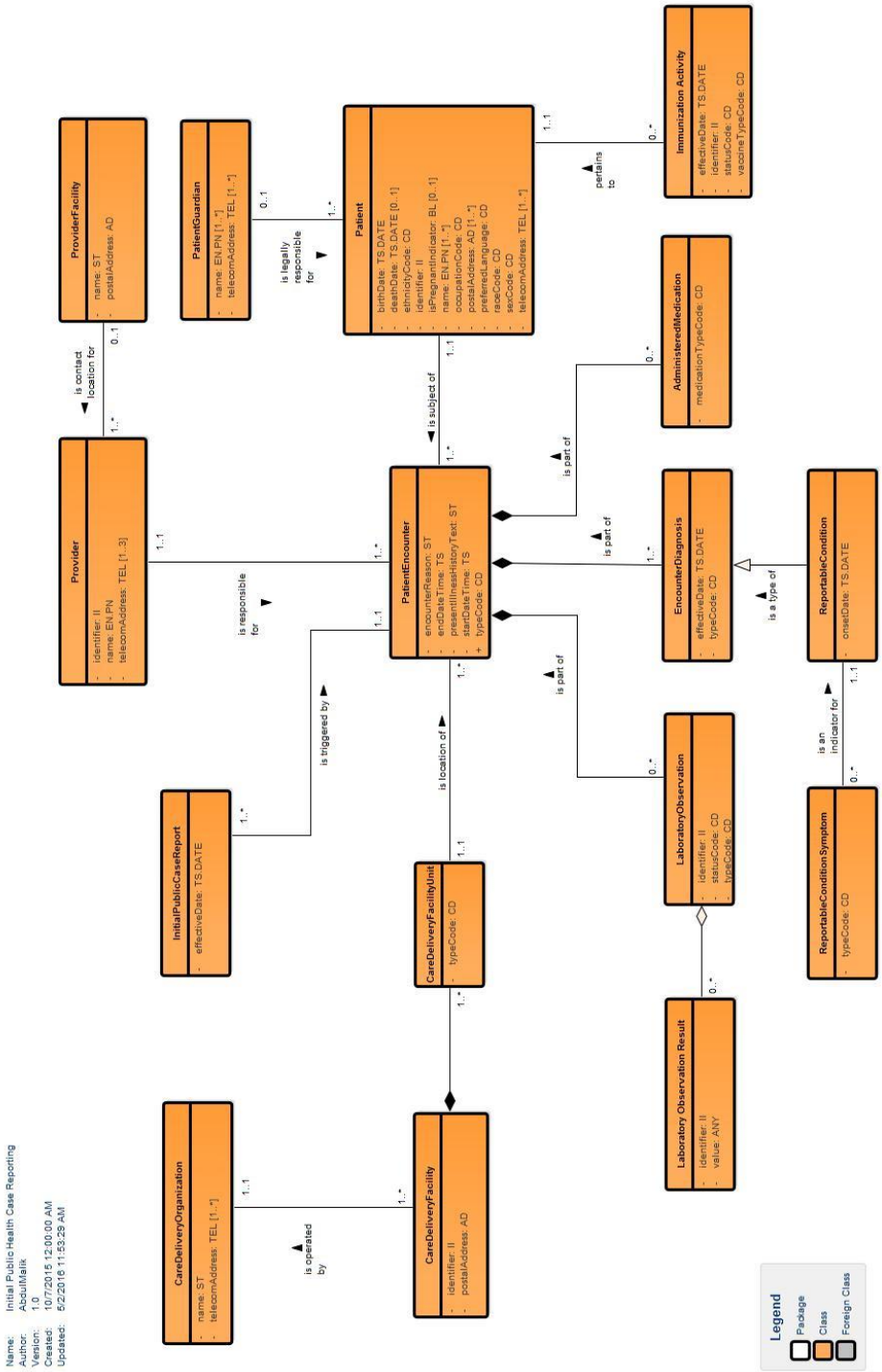
CSTE ELEMENT NAME	CSTE DESCRIPTION	RATIONALE / JUSTIFICATION
Facility Type	The type of facility where patient received or is receiving healthcare for the reportable condition (e.g., hospital, ambulatory, urgent care, etc.)	Used to determine the type of care setting in which patient is receiving care for the reportable condition
Facility Phone	The facility's phone number with area code	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Facility Address	The mailing address for the facility where patient received or is receiving healthcare for the reportable condition. Must include street address, city/town, county, state, and zip code	Need provider's contact information in order to follow up appropriately for reportable event to ensure appropriate treatment, identify contact exposures, etc.
Patient ID Number	Patient social security number, medical record number, or other identifying value as required or allowed under jurisdictional laws governing health data exchange	Identification and contact; jurisdictions may select which they can receive based on laws governing public health data exchange
Patient Name	All names for the patient, including legal names and aliases. Must include the name type (i.e., legal or alias), first name, middle name, and last name	Identification and contact
Parent/Guardian Name	All names for the patient's parent or guardian, including legal names and aliases (if patient age is < 18 years). Must include name type (i.e., legal or alias), first name, middle name, and last name	For appropriate contact with minors
Patient or Parent/Guardian Phone	All phone numbers and phone number types for the patient or parent/guardian	Contact Patient
Patient or Parent/Guardian Email	The email address for the patient or the patient's parent/guardian.	Contact Patient
Street Address	All addresses for the patient, including current and residential addresses. Must include street address, apartment or suite number, city or town, county, state, zip code, and country	Case Assignment, analysis and visualization, matching

CSTE ELEMENT NAME	CSTE DESCRIPTION	RATIONALE / JUSTIFICATION
Birth Date	The patient's date of birth	Appropriate identification, appropriate identification of minors, risk; Necessary to determine patient age; matching electronic laboratory reports (ELR)
Patient Sex	The patient's biological sex (not gender)	Demographic reporting
Race	The patient's race	Demographic reporting
Ethnicity	The patient's ethnicity	Demographic reporting
Preferred Language	The patient's preferred language	Communication with Patient
Occupation	The patient's occupation	Identification of potential risk, transmission risk
Pregnant	The patient's pregnancy status	Appropriate treatment, follow-up, appropriate for scoring/risk ascertainment
Visit Date/Time	Date and time of the provider's most recent encounter with the patient regarding the reportable condition	Defines when the individual may have been ill; a point in time to which can link other potential cases of reportable event; necessary to ensure follow-up within key time frames/helps triage priority follow-up and ensure control measures are implemented in a timely way
Admission Date/Time	Date and time when the patient was admitted to the treatment facility; e.g., hospital	Key for epidemiologic investigation - important to know if hospitalized for severity of condition and to triage priority follow-up
History of Present Illness	Physician's narrative of the history of the reportable event. Hopefully a place where we can get information such as travel, contacts, etc. if captured	Indicator of reportable condition - most important descriptor of condition/ epidemiologic information - supports epidemiologic investigation ; epidemiologic relevant information
Reason for Visit	Provider's interpretation for the patient's visit for the reportable event	Indicator of reportable condition - most important descriptor of condition/ epidemiologic information - supports epidemiologic investigation
Date of Onset	The date of symptoms for the reportable event	Helps determine possible exposure and illness- calculate incubation period

CSTE ELEMENT NAME	CSTE DESCRIPTION	RATIONALE / JUSTIFICATION
Symptoms (list)	List of patient symptoms (structured) for the reportable event	We know if clinical symptoms signify a case of PH importance - confirm the need for PH follow up
Laboratory Order Code	Ordered tests for the patient during the encounter	Some lab test orders are reportable for suspected cases
Placer Order Number	Identifier for the laboratory order from the encounter	Potential value to linking electronic laboratory reports (ELR) to eICR
Diagnoses	The healthcare provider's diagnoses of the patient's health condition (all)	Would include something that is potentially reportable
Date of Diagnosis	The date of provider diagnosis	We want to know when they're diagnosed; integral to epidemiological investigation
Medications Administered (list)	List of medications administered for the reportable event	To find treatments that were prescribed; prophylaxis; we know if they've already been treated, lower on the list for PH (priority)
Death Date	The patient's date of death	Patient follow-up and epidemiological purposes
Patient Class	Whether patient is outpatient, inpatient, emergency, urgent care	

3.5 eICR Data Model

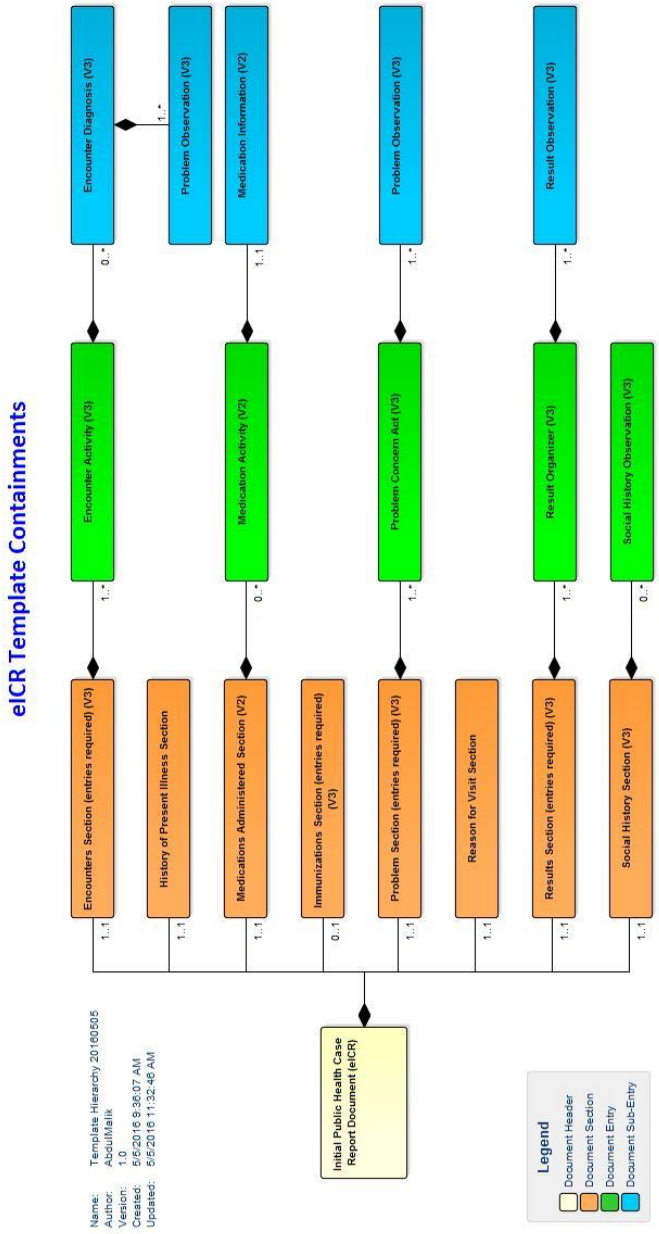
Figure 9. The eICR Data Model documents the important data that support clinical care and public health for an electronic initial public health case report.



3.6 Mapping of data elements to Data Model (Table 4)

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

3.7 eICR Template Hierarchy (Figure 10)



3.8 Mapping of elements to IG Templates (Table 5)

Data Element	IG Template	IG Constraint (Conformance Identifier)	Note
Date of the Report	US Realm Header (V3)	(CONF:1198-5256)	
Provider ID	eICR Initial Public Health Case Report Document	(CONF:2218-8)	This data element can repeat.
Provider Name	eICR Initial Public Health Case Report Document	(CONF:2218-25)	
Provider Phone	eICR Initial Public Health Case Report Document	(CONF:2218-24)	URL.scheme = 'tel:'. This data element can repeat.
Provider Fax	eICR Initial Public Health Case Report Document	(CONF:2218-24)	URL.scheme = 'tel:'. This data element can repeat.
Provider Email	eICR Initial Public Health Case Report Document	(CONF:2218-24)	URL.scheme = 'mailto:'. This data element can repeat.
Provider Facility/Office Name	eICR Initial Public Health Case Report Document	(CONF:2218-26)	
Provider Address	eICR Initial Public Health Case Report Document	(CONF:2218-27)	
Facility ID Number	eICR Initial Public Health Case Report Document	(CONF:2218-13)	
Facility Name	eICR Initial Public Health Case Report Document	(CONF:2218-33)	
Facility Type	eICR Initial Public Health Case Report Document	(CONF:2218-14)	
Facility Phone	eICR Initial Public Health Case Report Document	(CONF:2218-34)	URL.scheme = 'tel:'. This data element can repeat.
Facility FAX	eICR Initial Public Health Case Report Document	(CONF:2218-34)	URL.scheme = 'tel:'. This data element can repeat.
Facility Address	eICR Initial Public Health Case Report Document	(CONF:2218-32)	This data element can repeat.
Patient Class	US Realm Header (V3)	(CONF:2218-4)	
Patient ID Number	US Realm Header (V3)	(CONF:1198-5268)	This data element can repeat.
Patient Name	US Realm Header (V3)	(CONF:1198-5284)	This data element can repeat.
Patient Phone	US Realm Header (V3)	(CONF:1198-5280)	URL.scheme = 'tel:'. This data element can repeat.
Patient Email	US Realm Header (V3)	(CONF:1198-5280)	URL.scheme = 'mailto:'. This data element can repeat.

Data Element	IG Template	IG Constraint (Conformance Identifier)	Note
Parent/Guardian Name	US Realm Header (V3)	(CONF:1198-5386)	This data element can repeat.
Parent/Guardian Phone	US Realm Header (V3)	(CONF:1198-5382)	URL.scheme = 'tel:'. This data element can repeat.
Parent/Guardian Email	US Realm Header (V3)	(CONF:1198-5382)	URL.scheme = 'mailto:'. This data element can repeat.
Street Address	US Realm Header (V3)	(CONF:1198-5271)	This data element can repeat.
Birth Date	US Realm Header (V3)	(CONF:1198-5298)	
Patient Sex	US Realm Header (V3)	(CONF:1198-6394)	
Race	US Realm Header (V3)	(CONF:1198-5322), (CONF:1198-7263)	This data element can repeat.
Ethnicity	US Realm Header (V3)	(CONF:1198-5323), (CONF:1198-32901).	This data element can repeat.
Preferred Language	US Realm Header (V3)	(CONF:1198-5407)	This data element can repeat.
Occupation	Social History Observation (V3)	(CONF:1198-8559)	Observation.code = SCTID: 14679004 This data element can repeat.
Pregnant	Problem Observation (V3)	(CONF:1198-9058)	During the DSTU period, the use of the Problems Observation template to indicate pregnancy is being evaluated. The recommended SNOMED value codes are '60001007' Not pregnant (finding), and '77386006' Patient currently pregnant (finding).
Hospital Unit	eICR Initial Public Health Case Report Document	(CONF:2218-14)	

Data Element	IG Template	IG Constraint (Conformance Identifier)	Note
Visit Date/Time	eICR Initial Public Health Case Report Document	(CONF:2218-20)	For outpatient encounters
Admission Date/Time	eICR Initial Public Health Case Report Document	(CONF:2218-20)	For Inpatient encounters
Discharge Date/Time	eICR Initial Public Health Case Report Document	(CONF:2218-21)	For Inpatient encounters
History of Present Illness	History of Present Illness Section	(CONF:81-7851)	This data element can repeat within the text element of this narrative only template.
Reason for Visit	Reason for Visit Section	(CONF:81-7839)	This data element can repeat within the text element of this narrative only template.
Date of Onset	Problem Observation (V3)	(CONF:1198-15603)	This data element can repeat.
Symptoms (list)	Problem Observation (V3)	(CONF:1198-9058)	This data element can repeat.
Lab Order Code	Result Organizer (V3)	(CONF:1198-7128)	This data element can repeat.
Laboratory Results	Result Observation (V3)	(CONF:1198-7133), (CONF:1198-7143)	Laboratory results require both an observation code and an observation value. This data element can repeat.
Filler Order Number	Result Organizer (V3)	(CONF:1198-7127)	This data element can repeat.
Diagnoses	Problem Observation (V3)	(CONF:1198-9058)	Observation.code = LOINC: 29308-4. This data element can repeat.
Date of Diagnosis	Encounter Activity (V3)	(CONF:1198-8715)	This data element can repeat.
Medications Administered (list)	Medication Information (V2)	(CONF:1098-7412)	This data element can repeat.
Death Date	eICR Initial Public Health Case Report Document	(CONF:1198-106)	
Immunization Status	Immunizations Section (entries required) (V3)	(CONF:2218-149)	

Appendix A — 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 above in the context of the section where they are used. This section serves to summarize the extensions and provide implementation guidance.

Extensions created for this guide include:

sdtc:raceCode	The raceCode extension allows for multiple races to be reported for a patient.
sdtc:ethnicGroupCode	The ethnicGroupCode extension allows for additional ethnicity groups for the recordTarget or subjectPerson.
sdtc:deceasedInd	The deceasedIndextension (= “true” or “false”) in the family history organizer on the related subject is used inside to indicate if a family member is deceased.
sdtc:deceasedTime	The deceasedTime extension in the family history organizer on the related subject allows for reporting the date and time a family member died.
sdtc:dischargeDispositionCode	The dischargeDispositionCode extension allows the provider to record a discharge disposition in an encounter activity.
sdtc:signatureText	The signatureText extension provides a location in CDA for a textual or multimedia depiction of the signature by which the participant endorses and accepts responsibility for his or her participation in the Act as specified in the Participation.typeCode. Details of what goes in the field are described in the HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1.

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

