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HITSP Patient Level Quality Data Document Component

HITSP/C38

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DOCUMENT CHANGE HISTORY

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FIGURES AND TABLES

1.0 INTRODUCTION

As an introduction to the HITSP Patient Level Quality Data Document Component, this section provides a high level overview of the information sharing scenario enabled by following this specification, provides a document map of the construct relationships for this specification, acknowledges the copyright protections that pertain, and provides links to key reference documents and background material. If you are already familiar with this information, proceed to Section 2.0 Component Definition.

1.1 OVERVIEW

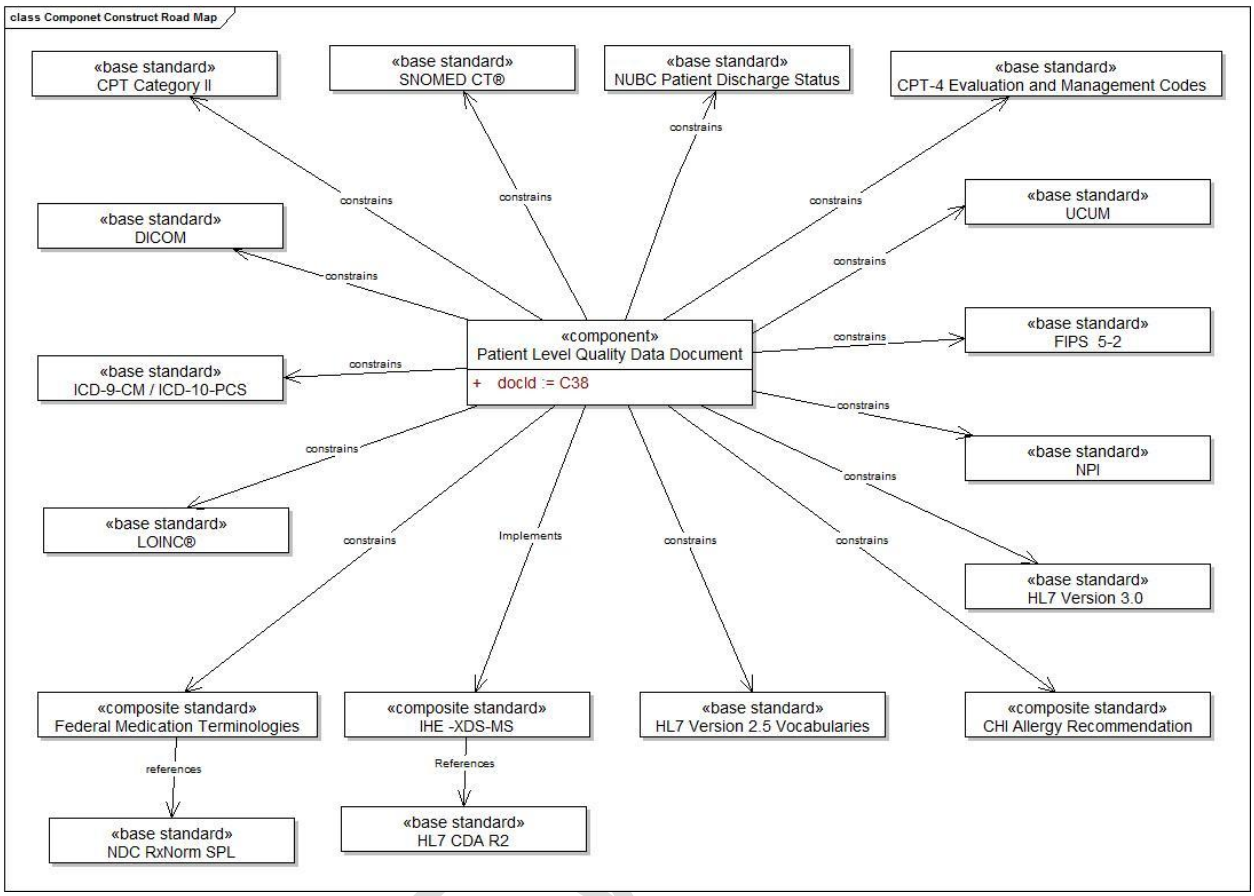
This section describes the contents of this specification and provides a high level definition of this Component and background information about the underlying standards that the Component is based on.

This Component supports the communication of patient level quality data for quality measurement in a document sharing environment. Patient encounter data are compiled from both the local systems and from longitudinal data available through a health information exchange prior to communicating the retrieved data described in this construct for analysis.

1.2 COMPONENT CONSTRUCT ROADMAP

Each HITSP specification is comprised of a suite of constructs that, taken as a whole, provide a detailed map to existing standards and specifications that will satisfy the requirements for the HITSP construct. The specification identifies and constrains standards where necessary, and creates groupings of specific actions and actors to further describe the relevant contexts using components and standards depicted in the diagram below. The most effective way to review the construct breakdown for any HITSP specification is to begin with the document indicated at the top of the diagram.

Figure 1.2-1 Component Construct Roadmap



1.3 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

1.4 REFERENCE DOCUMENTS

This section contains links to key reference documents and background material.

The HITSP Interoperability Specification Overview provides the background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. The document also provides a description of the HITSP process for healthcare standards harmonization and explains how to use the Interoperability Specifications and other related documents to inform your health IT product development or product refinement.

The conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications are contained in the HITSP Conventions List.

The acronyms used in this document are contained in the HITSP Acronyms List.

The HITSP Harmonization Framework describes the current framework within which the Interoperability Specifications are built.

This document references the Quality Detailed Use Case, June 18, 2007.

2.0 COMPONENT DEFINITION

A Component defines atomic constructs used to support an information exchange or to meet an infrastructure requirement. This is accomplished by:

(a) Referencing one or more underlying standards
(b) Specifying constraints and other rules for using the standards

2.1 CONTEXT OVERVIEW

This section provides a general description of the Component. It includes a detailed definition of the Component and the reason for its use. It also provides all the necessary background information that further describes the context in which the Component is needed, and the base or composite standard that the Component is based on.

The Patient Level Quality Data Component constrains the IHE XDS Medical Summary to support the communication of quality data for analysis and measurement. The specification includes constraints of location and vocabulary.

2.1.1 COMPONENT CONSTRAINTS

This section describes the constraints that limit the context in which the Component may be used. A constraint describes a rule that limits the use of the actors, actions or data within the given context, or to which the interactions must conform to be used within the described context. It is a description of the limits and scope of the interactions and can describe actions or events that are not part of the initial definition for the context.

Table 2.1.1-1 Component Constraints

Constraint
No applicable constraints. See 4.0 Appendix for informative details

2.1.2 COMPONENT DEPENDENCIES

This section describes any specific mapping criteria for the standards underlying the Component. It elaborates on the relationships between different standards used by this Component, and how they map to each other. Additional required mapping criteria not currently enforced by the underlying standards, and any specific elements that are required for this mapping to succeed, are also provided.

Table 2.1.2-1 Component Dependencies

Standard/HITSP Component	Depends On (Name of standard/HITSP component that it depends on)	Dependency Type (Pre-condition, post-condition, general)	Purpose (Reason for this dependency)
No applicable dependencies See 4.0 Appendix for informative details			

2.2 RULES FOR IMPLEMENTING

The following section documents the content of the Component. It provides the basics elements and secondary standards that are supported by this Component and the constraints that are being placed on those standards. Specifically, it describes the subset or constraints that are required for this Component, and the minimum attributes of the Component as it relates to the base or composite standards on which it is based.

Not applicable.

2.2.1 DATA MAPPING

This section describes the specific data elements used by this Component. Due to the potentially large number of data elements in a particular standard, only the fields that HITSP is constraining differently from the standard will be described here.

2.2.1.1 Cross – Reference Table Key

The following table includes data element and information requirements derived from the list of quality measures provided by the Health Information Technology Expert Panel (HITEP). The final list of information requirements is pending. The final data dictionary will be used to inform the Interoperability Specification constructs.

Table 2.2.1.1-1 Data Element Cross Reference

DATA ELEMENTS CROSS REFERENCE	
Data Element	**Definition**
Data Element	Data element name/identifier.
Description	Quality data element description.
Source	Source of the data element – where the data was created.
Limit/Range / Vocabulary	Expected data values if data element has finite values. Pre-coordinated vocabulary value set name or coding system from which values may be drawn.

DATA ELEMENTS CROSS REFERENCE	
Destination / HL7 Context	Segment and field where the data element appears in the HL7 message and other context as required.
HL7 Data Type	HL7 data type for the data element – indicates format and processing requirements.
Conditions for Use	Describe all the prevailing conditions that are assumed to be in place to be able to use the data. State the need for a particular actor if one is involved.

2.2.1.2 Patient Level Quality Data Message Data Set

In fulfillment of data and information requirements #10, the following provisional data dictionary was generated by the Population Health Technical Committee based upon interpretation of measure requirements provided by the HITEP. This list is currently under review by the HITEP. Standards selected or under consideration by the HITSP Population Health Technical Committee to constrain the vocabularies used for interoperability are provided.

Table 2.2.1.2-1 Data Elements Cross Reference

DATA ELEMENTS CROSS REFERENCE	
Column	**Definition**
AHIC Data Element	Data element name/identifier as listed by American Health Information Community Expert Panel for the Identification of Core Data Elements and Prioritization of AQA and HQA Performance Measures for Electronic Healthcare Information Systems
Definition	Data element description as listed by American Health Information Community Expert Panel for the Identification of Core Data Elements and Prioritization of AQA and HQA Performance Measures for Electronic Healthcare Information Systems
Data Type	Type of data that is collected with this data element (coded, numeric, text, date/time)
Terminology	Expected data values if data element has finite values. CHI-domain recommendations were followed if available
Comments	Pertinent comments and usage

Table 2.2.1.2-2 Base Facility Data Elements

BASE FACILITY DATA ELEMENTS				
AHIC Data Element	**Definition**	**Data Type**	**Selected Standards**	**Comments**
Facility Identifier	Unique facility identifier.	Numeric	CMS IDs	
Facility Name	Name of facility	String		
Facility Location	City and State	Coded	FIPS	Can be used for practice location

Table 2.2.1.2-3 Patient Data Elements

PATIENT DATA ELEMENTS				
AHIC Data Element	**Definition**	**Data Type**	**Selected Standards**	**Comments**
Pseudonymized Data Linker	A unique, randomly generated, encoded number that links to patient-level information (i.e., name and address) retained at the facility	Alphanumeric		Pseudo identifier resulting from the pseudonymization process.
Encounter Date/Time	Time of the patient presentation for care ED arrival time (initial triage time) or the registration time for inpatients, or check-in time for ambulatory settings.	Date/time field	HL7 Timestamp	Expected on ADT^A04 Registration (Outpatient and ED settings) ADT^A01 Admit transactions (Inpatients)
DOB	Date of birth	Date field	HL7 Timestamp	NOTE: May not be passing DOB for age over 89 due to HIPAA requirements
Gender/sex	Patient sex/gender	Coded	HL7 2.5 Administrative Sex Codes	
Visit data	Electronic medical records billing codes		CPT Evaluation and Management Codes	
Patient Class	General type of patient, *e.g.*, Inpatient, Outpatient, Emergency	Coded	HL7 2.5 Patient Class Codes	
Discharge Date/time	Time of inpatient discharge or release from ED	Date field	HL7 Timestamp	
Discharge Disposition	Patient's anticipated location or status following the encounter (e.g. death, transfer to home/hospice/snf/AMA) – uses standard claims-based codes	Coded	Universal Billing codes (UB-92/NUBC CURRENT UB DATA SPECIFICATIONS MANUAL)	Expected in Discharge (ADT^A03) transactions only
Discharged to location	General location to where the patient was discharged or transferred	Coded	Universal Billing codes (UB-92/NUBC CURRENT UB DATA SPECIFICATIONS MANUAL)	Expected in Discharge (ADT^A03) transactions only
Deceased indicator	Indicator on record that the patient is deceased	Coded		
Deceased Date/time	If patient has died, deceased date/time	Date/time		

Table 2.2.1.2-4 Clinical Data Elements

CLINICAL DATA				
AHIC Data Element	**Definition**	**Data Type**	**Selected Standards**	**Comments**
Procedures and diagnostic tests				
Procedure Ordered	Study that was ordered (e.g. laboratory, radiology, echo LVEF) Must include order date/time, and procedure name. This will be the name of the ordered procedure, radiology or laboratory service as the ordering system knows it Assumption –Order date/time useful for measures for measures that ask whether the order was written	Coded	SNOMED CT, LOINC/DICOM, CPT Category II[1]	Possible Gap in reconciling data with workflow NOTE: this is subject to harmonization of terms across HITSP GAP: Recommend to LOINC, SNOMED CT, and CPT to develop AND harmonize a suitable coded value set to express order test name and code values
Procedure Performed	Study exclusive of laboratory; (e.g. radiology, echo LVEF). It is expected that some procedures will be found as components of a physical examination. Must include procedure date/time Supports measures based on a prior trigger event.	Coded	CPT, ICD-9, SNOMED CT	
Vital signs	For the purpose of this IS version, BP systolic and diastolic are the only vital signs required	Numeric		Passed as two separate observations Included timestamp for when the observation was done
Pulse Oximetry	Pulse oximetry value	Numeric		Passed as observation Included timestamp for when it was done

[1] We recognize the existence of CPT II as a new administrative coding system to collect measurement required data elements. The long-term goal for interoperability is to use clinical terminology allowing the repurposing of data created as part of routine clinical care delivery. For the short term, CPT II codes may be useful to capture required data for measurement calculation, especially with respect to exclusion criteria inherent in many measures. The Technical Committee has recommended standards and terminologies to enable clinical data element standardization which will require work effort by EHRs, receiving systems and clinical measurement and guideline developers. Such standardization will support repurposing of routine clinical care data for quality measurement without interposition of additional coding schema such as CPT II.

CLINICAL DATA				
AHIC Data Element	**Definition**	**Data Type**	**Selected Standards**	**Comments**
Allergies	(e.g. hypersensitivity reactions)	Coded	CHI Allergy Recommendation (HL7 Allergen type code /Allergen reaction code – use SNOMED code here/ and need coded value for Allergen (UNII – Unique Ingredient Identifier from FDA, RXNORM – including brand-name, NDF-RT – to drug class rather than brand name), SNOMED CT for allergy type, severity, reaction EPA Substance Registry System for non-drug chemicals)	VA created list of allergic reactions might be contributed to an SDO and considered here (Reactants are covered in CHI) NOTE: Assumption – allergies/adverse reactions only related to medications
Substance Intolerance	Actual or anticipated side effects that may represent exclusions for measures.	Coded	SNOMED CT ICD-9	
Diagnoses	Administrative diagnoses (e.g. those used for billing). Will use the Patient Class field to identify encounter type (inpatient, outpatient, etc.) Administrative Diagnosis must include diagnosis type (e.g. admitting, working, final) and priority (e.g. priority=1).	Coded	ICD9-CM/ICD10	The previously available SNOMED CT to ICD9-CM statistical mapping has been enhanced to include a SNOMED CT to ICD9-CM rule based reimbursement map. The mapping has been completed and is currently being evaluated by the NLM and vendor community. Further validation will be done by AHIMA
Problems	Interdisciplinary patient issues, both chronic and acute, active and inactive. It is expected that behavioral risk factors (e.g. smoking) would be present on the problem list, significant past procedures or diagnoses, and any significant family history that would reflect a risk factor. While we recognize that ICD9-CM is currently used in many systems, evolution toward SNOMED is preferred. Reason for admission is not a separate data element on this list but could be reflected as a problem.	Coded	SNOMED CT ICD9-CM	

CLINICAL DATA				
AHIC Data Element	**Definition**	**Data Type**	**Selected Standards**	**Comments**
Documentation of clinician-to-clinician communication	Consult between clinicians (e.g. an eye exam with appropriate components)	Coded	Consultation note coded in SNOMED CT	SEE GAP NOTE: HL7 Consultation notes out for ballot (constraint on CCD) See Gap Derived Element and phase II plans Refer to the procedure section for procedure occurrence and result.
Discharge instructions	Documentation of communication: provider to patient (paper or verbal)	Coded	SNOMED CT, LOINC	LOINC for the observation (variable), and SNOMED CT for the result May be a need for other communication methods
Provider Identifier	Unique provider (clinician) identifier	Coded	NPI	Need clarification from HITEP regarding provider-patient relationship (e.g. attending, admitting, PCP, consultant) required for attribution. GAP: Business rule applied to the attribution needs to be defined.
Care Classification	Care classification of comfort measures only, DNR, or DNI (e.g. palliative care)	Coded	SNOMED CT	(See SNOMED CT Procedure 133918004)385897008 – Care Regimes Management

Table 2.2.1.2-5 Medications

MEDICATION ELEMENTS				
AHIC Data Element	**Definition**	**Data Type**	**Selected Standards**	**Comments**
Medication Ordered	Expressed as CPT – therapy; May be expressed in a medication list. Drug name/standardized code, and ordered date/time is minimally required for measures that look at if a particular drug was ordered. Dose, strength, dispensed amount, and number of refills may also be necessary to express the selected measure.	Alpha-numeric	Federal Medication Terminologies, CPT	Prefer RxNORM, NDF-RT Requires some differentiation of order versus prescribed. This information may be determined by a secondary source such as a discharge medication list, but it is unclear from the measure description
Authorizing provider	Medication prescriber/orderer	Coded	NPI	
Medication administered	Medication administered in a controlled setting such as ED, ambulatory surgical centers, inpatient. Timing (first dose, last dose) depends upon the measure.	Coded	RxNorm	NOTE: This data element is expected to be harmonized with the output of the HITSP medication management efforts

MEDICATION ELEMENTS				
AHIC Data Element	**Definition**	**Data Type**	**Selected Standards**	**Comments**
Medication Administration date/time	Date/time that medication was administered in a controlled setting such as ED, ambulatory surgical centers, inpatient	Date field	HL7 Timestamp	NOTE: This data element is expected to be harmonized with the output of the HITSP medication management efforts
Derived attributes (e.g. continuous use say of beta blockers over 6 months)	Continuous use or other derived variables need to have base elements and algorithm needed to compute so patient level data can be sent to aggregator for computing by the physician. The measure definition needs to clearly identify what data elements are required to calculate 'continuous use'			Understood to be a lower priority

Table 2.2.1.2-6 Laboratory/Microbiology Result Data

LABORATORY/MICROBIOLOGY RESULTS				
AHIC Data Element	**Definition**	**Data Type**	**Selected Standards**	**Comments**
Resulted laboratory test	The identifier code for the specific test component resulted	Coded	LOINC Laboratory Test Identifiers include analytes, specimen source, methods, and sensitivity tests for drugs	
Laboratory result value	Laboratory test results including susceptibilities, serologies, non-organisms; coded value	Numeric or Coded	SNOMED-CT (non-numeric laboratory such as organisms and other coded results)	
Result unit	Units for numeric result context	Coded	Unified Code for Units of Measure (UCUM) Expressions	GAP: Units may be text data currently
Report date/time	Laboratorymicrobiology result date/time	Date	HL7 Timestamp	
Result status	Status of report (preliminary, final, corrected)	Coded	HL70123 Result Status	
Test interpretation	Interpretation of test result by the laboratory, including the susceptibility test interpretation	String	HL70078 Abnormal Flags	

Table 2.2.1.2-7 Results for Radiology and Other Studies

RADIOLOGY AND OTHER STUDY RESULT DATA				
AHIC Data Element	**Definition**	**Data Type**	**Selected Standards**	**Comments**
Report date/time	Report/Reading Date. This date is updated with report corrections and addenda	Date/time	HL7 Timestamp	

RADIOLOGY AND OTHER STUDY RESULT DATA				
AHIC Data Element	**Definition**	**Data Type**	**Selected Standards**	**Comments**
Report Status	Status of the report (preliminary, final, corrected) is required in a result message"	Coded	HL70123 Result Status	
Test Performed	Radiology and other diagnostic test information (e.g. radiology findings, echocardiogram results, LVEF)	Coded	CPT+ Textual Description which can include modification	
Impressions	Radiologist's diagnosis and impressions	Alphanumeric	SNOMED CT Or ICD9-CM	May be passed as an observation with LOINC tag: '19005-8^X-RAY IMPRESSION^LN'

2.2.1.3 Mapping Table

This section describes the specific data elements used by this Component. Due to the potentially large number of data elements in a particular standard, only the fields that HITSP is constraining differently from the standard will be described here.

Note: The location in the "Destination" column can be considered to be "pseudo-XPath". While these are not properly formed XPath expressions in all cases, these destinations should allow a reader familiar with XPath notation to identify the location of the data element in a CDA document. Descriptions are included next to LOINC and SNOMED codes to aid comprehension.

Table 2.2.1.3-1 Patient Data Mapping

Data Element	Description	Limit/Range of Values	Data Source	Destination	Requirements/ Pre-conditions
Pseudonymized Patient ID /Randomized Data Linker	Unique, randomly generated, encoded number that links to patient-level information (i.e., name, address) retained at the facility	CX		ClinicalDocument/recordTarget/patientRole/id	Required in every document
Encounter Date/Time	Time of the patient presentation for care: ED arrival time (initial triage time) or the registration time for inpatients, or check-in time for ambulatory settings.	HL7 Timestamp, TS		ClinicalDocument/componentOf/encompassingEncounter/effectiveTime	Required element
DOB	Date of birth	HL7 Timestamp, TS		ClinicalDocument/recordTarget/patientRole/patient/birthTime	
Sex	Patient sex/gender	HL7 2.5 Table 001 Administrative Sex, IS (coded)		ClinicalDocument/recordTarget/patientRole/patient/administrativeGenderCode	

Data Element	Description	Limit/Range of Values	Data Source	Destination	Requirements/ Pre-conditions
Visit data	Electronic medical records billing codes	CPT Evaluation and Management Codes , CE (coded)		ClinicalDocument/component/structuredBody/component/section/code/	
Patient Class	General type of patient, e.g., Inpatient, Outpatient, Emergency.	HL7 2.5 Table 0004 Patient Class , IS (coded)		ClinicalDocument/componentOf/encompassingEncounter/code	
Discharge Date/time	Time of Inpatient discharge or release from ED	HL7 Timestamp , TS		/ClinicalDocument/componentOf/encompassingEncounter/effectiveTime or /ClinicalDocument/componentOf/encompassingEncounter/effectiveTime/high	For hospital stays, effectiveTime/high should be used to represent discharge time; for very brief encounters, a single time could be used to represent the start and end of the encounter
Discharge Disposition	Patient's anticipated location or status following the encounter (e.g. death, transfer to home/hospice/snf/AMA) – uses standard claims-based codes	Universal Billing codes (UB-92/NUBC CURRENT UB DATA SPECS MANUAL , IS (coded)		ClinicalDocument/componentOf/encompassingEncounter/dischargeDispositionCode NOTE: Only required where patient has been discharged (e.g. not usually relevant to ambulatory care)	Expected for hospital encounters when the encounter is complete.
Deceased indicator	Indicator on record that the patient is deceased	HL7 Table 0136Yes/No Indicator , Coded (Y/N)		ClinicalDocument/component/structuredBody/component/section/code/@code= »SUMMARY OF DEATH 47046-8 «	
Deceased Date/time	If patient has died, deceased date/time	HL7 Timestamp		ClinicalDocument/component/structuredBody/component/section/entry/observation (code= »DATE OF DEATH 31211-6 »)/effectiveTime/	

Data Element	Description	Limit/Range of Values	Data Source	Destination	Requirements/ Pre-conditions
Problem Data					
Problems	Interdisciplinary patient issues, both chronic and acute, active and inactive. It is expected that behavioral risk factors (e.g. smoking) would be present on the problem list, significant past procedures or diagnoses, and any significant family history that would reflect a risk factor. While we recognize that ICD9-CM is currently used in many systems, evolution toward SNOMED is preferred. Reason for admission is not a separate data element on this list but could be reflected as a problem.	SNOMED CT[2] ICD9-CM		ClinicalDocument/component/structuredBody/component/section code/@code="PROBLEMS LIST 11450-4" /entry/observation	HL7 Definition Chapter 12: A **problem** of a given individual can be described by formal diagnosis coding systems (e.g., DRGs, NANDA Nursing Diagnosis, ICD9, DSM, etc.) or by other professional descriptions of healthcare issues affecting individual. Problems can be short- or long-term, chronic or acute, and have a status. In a longitudinal record, all problems may be of importance in long-term care of an individual, and may undergo changes in status repeatedly. Problems are identified during patient visits, and may span multiple visits, encounters, or episodes of care.
Allergies	Allergies/adverse reactions only related to medications or food substances	CHI Allergy Recommendation		ClinicalDocument/component/structuredBody/component/section/code/@code="Allergies, Adverse Reactions, Alerts 48765-2"	
Substance Intolerance	Actual or anticipated side effects that may be exclusions for measures.	SNOMED CT[2] ICD-9, CE (coded)		ClinicalDocument/component/structuredBody/component/section/code/@code="Allergies, Adverse Reactions, Alerts 48765-2"	
Diagnosis Data					
Diagnoses	Administrative diagnoses (e.g. those used for billing). Will use the Patient Class field to identify encounter type (inpatient, outpatient, etc.)	ICD9-CM[2]/ICD10		/ClinicalDocument/component/structuredBody/component/section code/@code="Hospital Discharge Dx 11535-2" or "History of Past Illness 11348-0" /entry/observation/value entry/observation/code/@code should be SNOMED CT code "established diagnosis14657009 »	Expecting mostly ICD-9 diagnosis codes, but SNOMED CT or other vocabulary may be used.

Data Element	Description	Limit/Range of Values	Data Source	Destination	Requirements/ Pre-conditions
Diagnosis Type	Type of diagnosis (admitting, working, final)			/ClinicalDocument/component/structuredBody/component/section/entry/observation/statusCode	
Diagnosis Priority	Used to indicate Principal diagnosis in message			/ClinicalDocument/component/structuredBody/component/section/entry/observation/priorityCode/code/@code	
Vital Signs					
Blood Pressure - Diastolic Observation Date/Time	Systolic/Diastolic blood pressure measurement and the date/time that it was performed.	LOINC for observation identifier, UCUM Blood Pressure Unit Code, NM/SN (Numeric or Structured Numeric)		ClinicalDocument/component/structuredBody/component/section code="VITAL SIGNS 8716-3"/observation	
Blood Pressure - Systolic Observation Date/Time	Systolic/Diastolic blood pressure measurement and the date/time that it was performed.	LOINC for observation identifier, UCUM Blood Pressure Unit Code, NM/SN (Numeric or Structured Numeric)	Clinical system	ClinicalDocument/component/structuredBody/component/section code="VITAL SIGNS 8716-3"/observation	
Pulse Oximetry Observation Date/Time	Pulse oximetry reading and the date/time that it was performed.	LOINC for observation identifier, NM/SN (Numeric or Structured Numeric)	Clinical system	ClinicalDocument/component/structuredBody/component/section code="VITAL SIGNS 8716-3"/observation	NOTE: Optional, additional to the HITEP data element type list

Data Element	Description	Limit/Range of Values	Data Source	Destination	Requirements/ Pre-conditions
Procedures and Diagnostic Tests					
Procedure Ordered	Study that was ordered (e.g. laboratory, radiology, echo LVEF) Must include order date/time, and procedure name. This will be the name of the ordered procedure, radiology or laboratory service as the ordering system knows it Assumption –Order date/time useful for measures for measures that ask whether the order was written	SNOMED CT, LOINC/DICOM, CE (Coded)	Order Entry system	ClinicalDocument/component/structuredBody/component/section/entry/procedure @moodCode="RQO"/code)	NOTE: this is subject to harmonization of terms across HITSP GAP: Recommend to LOINC, SNOMED CT, and CPT to develop AND harmonize a suitable coded value set to express order test name and code values
Procedure Performed	Study exclusive of laboratory; (e.g. radiology, echo LVEF). It is expected that some procedures will be found as components of a physical examination. Must include procedure date/time Supports measures based on a prior trigger event.	CPT, ICD9-CM, SNOMED CT, CE (Coded)		ClinicalDocument/component/structuredBody/component/section/entry/procedure @moodCode="EVN"/code)	
Provider Identifier	Unique provider (clinician) identifier	NPI		ClinicalDocument/componentOf/encompassingEncounter/encounterParticipant/assignedEntity/ID	Need clarification from HITEP on provider-patient relationship (e.g. attending, admitting, PCP, consultant) needs for attribution. Provider roles are given as reference but require resolution of GAP to implement. GAP: Business rule applied to attribution needs to be defined.

Data Element	Description	Limit/Range of Values	Data Source	Destination	Requirements/ Pre-conditions
Provider Role	Function or responsibility assumed by a provider in context of a healthcare event. Role information documents a person's association with identified healthcare activity. Examples - primary care provider, transcriptionist, consulting physician.	TBD – See Overlap		ClinicalDocument/componentOf/encompassingEncounter/encounterParticipant/typeCode	The provider roles are provided as reference but require resolution of Overlap for full implementation. Overlap: Role term is used in various standards differently.
Other Clinical Data Elements					
Documentation of communication: provider to patient	Documentation of communication: provider to patient (paper or verbal) E.g., Discharge instructions	SNOMED CT[2], LOINC		ClinicalDocumen/component/structuredBody/component/section code/@code="Hospital Discharge Instructions 8653-8"	Likely to be text in existing systems, some may be codiried in nursing terminologies which can be mapped to SNOMED.
Documentation of clinician-to-clinician communications	Consult between clinicians (e.g. an eye exam with appropriate components)	Consultation note coded in SNOMED CT[2]		ClinicalDocument/component/structuredBody/component/section/ where ClinicalDocument/code/@code is any of a long list of "CONSULTATION NOTE" document types in LOINC (see Table 147 in HL7 CDA specification for representative list.)	NOTE: HL7 Consultation notes out for ballot (constraint on CCD) SEE GAP: Derived Element and phase II plans. Refer to procedure section for procedure occurrence, result
Care Classification	Care classification of comfort measures only, DNR, or DNI (e.g. palliative care) or history of enrollment in a clinical trial, which may be used to exclude from a particular quality measure.	SNOMED CT[2]		ClinicalDocument/component/structuredBody/component/section code/@code="Advanced Directives 42348-3"	(See SNOMED CT Procedure 133918004)385897008 – Care Regimes Management GAP: "Comfort level only" is inconsistently defined and applied, needs standardized for equal application of measures and exclusion criteria. Referred to HITEP.

Data Element	Description	Limit/Range of Values	Data Source	Destination	Requirements/ Pre-conditions
Medication Data					
Medication Ordered	Expressed as CPT – therapy; May be expressed in a medication list. Drug name/standardized code, and ordered date/time is minimally required for measures that look at if a particular drug was ordered. Dose, strength, dispensed amount, and number of refills may also be necessary to express the selected measure.	Federal Medication Terminologies, CPT, CE (Coded)		ClinicalDocument/component/structuredBody/component/section/entry/substanceAdministration @moodCode= »RQO »	Prefer RxNORM, NDF-RT
Authorizing provider	Medication prescriber/orderer	NPI (See PIX/PDQ), XCN (Extended Coded Name)		ClinicalDocument/componentOf/encompassingEncounter/encounterParticipant/assignedEntity	
Medication administered	Medication administered in a controlled setting such as ED, ambulatory surgical centers, inpatient. Timing (e.g., which dose, first, last) depends upon the measure.	RxNorm, CE (Coded)		ClinicalDocument/component/structuredBody/component/section/entry/substanceAdministration @moodCode= »EVN »	NOTE: This data element is expected to be harmonized with the output of the HITSP medication management efforts
Medication administered Route	Route of medication administration	RxNorm, CE (Coded)		ClinicalDocument/component/structuredBody/component/section/entry/substanceAdministration @moodCode= »EVN »/routeCode/@code	May use HL7 Table 0162 Route of Administration
Medication Administration date/time	Date/time that medication was administered in a controlled setting such as ED, ambulatory surgical centers, inpatient	HL7 Timestamp, TS (Timestamp)		ClinicalDocument/component/structuredBody/component/section/entry/substanceAdministration @moodCode= »EVN »/effectiveTime	NOTE: This data element is expected to be harmonized with the output of the HITSP medication management efforts

Data Element	Description	Limit/Range of Values	Data Source	Destination	Requirements/ Pre-conditions
Derived attributes (e.g. continuous use say of beta blockers over 6 months)	Continuous use or other derived variables need to have base elements and algorithm needed to compute so patient level data can be sent to aggregator for computing by the physician. The measure definition needs to clearly identify what data elements are required to calculate 'continuous use'				Understood to be a lower priority. GAP - Measures need to define derivation for accurate implementation.
Resulted test	The identifier code for the specific test component resulted	LOINC Laboratory Test Identifiers include analytes, specimen source, methods, and sensitivity tests for drugs, CE (Coded)		ClinicalDocument/component/structuredBody/component/section code/@code= "Laboratory Report 11502-2"/entry/observation/code/@code	
Result value	Laboratory test results including susceptibilities, serologies, non-organisms; coded value	SNOMED-CT[2] (non-numeric laboratory such as organisms and other coded results), SN or NM (Numeric) or CE (Coded)		ClinicalDocument/component/structuredBody/component/section/entry/observation/value	
Result unit	Units for numeric result context	Unified Code for Units of Measure (UCUM) Expressions, CE (Coded)		ClinicalDocument/component/structuredBody/component/section/entry/observation/value/@unit	GAP: Units may be text data currently
Report date/time	Laboratorymicrobiology result date/time	HL7 Timestamp, TS (Timestamp)		ClinicalDocument/component/structuredBody/component/section/entry/observation/effectiveTime	
Result status	Status of report (preliminary, final, corrected)	HL70123 Result Status, ID (Coded)		ClinicalDocument/component/structuredBody/component/section/entry/observation/statusCode	
Test interpretation	Interpretation of test result by the laboratory, including the susceptibility test interpretation	HL70078 Abnormal Flags, IS (Coded)		ClinicalDocument/component/structuredBody/component/section/entry/observation/interpretationCode	

Data Element	Description	Limit/Range of Values	Data Source	Destination	Requirements/ Pre-conditions
Test Performed	Radiology and other diagnostic test information (e.g. radiology findings, echocardiogram results, LVEF)	CPT+ Textual Description which can include modification		ClinicalDocument/component/structuredBody/component/section code/@code="Studies Summary 30954-2"/entry/observation/code/@code	
Report date/time	Report/Reading Date. This date is updated with report corrections and addenda	HL7 Timestamp		ClinicalDocument/component/structuredBody/component/section code/@code="Studies Summary 30954-2" /entry/observation/effectiveTime)	
Result status	Status of report (preliminary, final, corrected)	HL70123 Result Status		ClinicalDocument/component/structuredBody/component/section code/@code="Studies Summary 30954-2" entry/observation/statusCode)	
Result value	Study findings exclusive of laboratory (e.g., radiology findings, echocardiogram LVEF)	DICOM (structured report), SNOMED-CT[2] ICD9-CM/ICD-10, CPT Category II[1]		ClinicalDocument/component/structuredBody/component/section code/@code="Studies Summary 30954-2"/entry/observation/code/@code	
Impressions	Interpretation of study, by provider of service including diagnosis and impressions	DICOM (structured report), SNOMED CT[2] Or ICD9-CM		ClinicalDocument/component/structuredBody/component/section code/@code="Studies Summary 30954-2"//entry/observation/text	Most likely text (alphanumeric)

2.2.2 GUIDELINES AND EXAMPLES

This section provides additional guidelines and examples that support the underlying base or composite standards for this Component. It describes how these specifications differ from the underlying standards, and provides guidelines and examples for implementation.

No additional information at this time.

2.3 LIST OF STANDARDS

It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts. The following standards are used to implement this Component specification:

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Table 2.3-1 List of Standards

Standard	Description
American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4)	A uniform coding system used primarily to identify medical services and procedures furnished by physicians and other healthcare professionals. Visit www.ama-assn.org for more information
Centers for Medicare and Medicaid Services (CMS) National Provider Identifier (NPI)	NPI is a unique 10-digit identification number issued to health care providers in the United States by the Centers for Medicare and Medicaid Services (CMS). All individual HIPAA covered healthcare providers (physicians, nurses, dentists, chiropractors, physical therapists, etc.) or organizations (hospitals, home health care agencies, nursing homes, residential treatment centers, group practices, laboratories, pharmacies, medical equipment companies, etc.) must obtain an NPI for use in all HIPAA standard transactions, even if a billing agency prepares the transaction. Once assigned, a provider's NPI is permanent and remains with the provider regardless of job or location changes. Visit www.cms.gov for more information.
Consolidated Health Informatics (CHI)	The Consolidated Health Informatics (CHI) initiative is one of the Office of Management and Budget's (OMB) eGov initiatives. CHI is a collaborative effort to adopt health information interoperability standards, particularly health vocabulary and messaging standards, for implementation in federal government systems. Originally, CHI identified a portfolio of 24 health domains that later expanded to 27. CHI adopted 20 uniform standards for electronic exchange of clinical information to be used across the federal health enterprise. Phase I ended in May 2004. In Phase II, CHI is focusing on Implementation of adopted standards, Maintenance of adopted standards, and Identification and adoption of new standards. Visit www.hhs.gov for more information.
College of American Pathologists Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)[2]	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. Visit www.ihtsdo.org for more information
Digital Imaging and Communications in Medicine (DICOM) Attribute Level Confidentiality Supplement: # 55	Adds a mechanism for selective protection of individual attributes within arbitrary DICOM service-object pair (SOP) instances. It may be used to achieve protection of identifying information, e.g., a reversible anonymization or pseudonymization of DICOM SOP instances while continuing to use unmodified lower level message and protocol services for network transfer, storage, and media exchange of composite image information objects. Visit medical.nema.org for more information

[2] SNOMED CT has integrated several of the ANA recognized nursing terminologies (Omaha System, CCC, NIC, NANDA, NOC, PNDS). LOINC, ICNP (International Classification of Nursing Practice), ABC Codes and NMMDS (Nursing Management Minimum Data Set) have not yet been fully mapped to SNOMED. These additional mappings must occur. As content evolves within specific standard nursing terminologies, as long as nursing terminologies maintain the mapping relationships with SNOMED CT, they will be fully compatible with interoperability. For purposes of interoperability with respect to the ONC Quality Use Case, mapping is required through SNOMED CT. While there is established value for individual interface nursing terminologies (e.g. CCC and Omaha System, both in the public domain), for collection of data, interoperability within the scope of the Use Case is best managed with SNOMED CT. The need to enhance visibility of nursing and other disciplines can best be managed through specific use cases developed in the future for that purpose. Therefore, SNOMED CT is the identified terminology for use in the Quality Use Case.

Standard	Description
Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987	A set of two-digit numeric codes and a set of two-letter alphabetic codes for representing the 50 states, the District of Columbia and the outlying areas of the United States, and associated areas. The standard covers all land areas under the sovereignty of the United States, the freely associated states of Federated States of Micronesia and Marshall Islands, and the trust territory of Palau. Visit www.itl.nist.gov for more information. NOTE: ASC X12 transactions and ASC X12N Implementation Guides do not allow use of this standard; instead they require use of the U.S. Postal Service's National Zip Code and Post Office Directory -- which provides similar alphabetic code values
Federal Medication Terminologies	A set of controlled terminologies and code sets developed and maintained as part of a collaboration between the Food and Drug Administration, National Library of Medicine, Veterans Health Administration, National Cancer Institute and Agency for Healthcare Research and Quality related to medications, including medication proprietary and nonproprietary names, clinical drug code (RxNorm); ingredient names and Unique Ingredient Identifiers (UNII); routes of administration, dosage forms, and units of presentation from the NCI Thesaurus (NCIt); and certain pharmacological drug classes from the National Drug File Reference Terminology (NDF-RT) The Federal Medication Terminology leverages medication models maintained by the Food and Drug Administration (ex. UNII, NDC Codes), National Library of Medicine (RxNorm), the Veterans Health Administration (NDF-RT), and the National Cancer Institute (NCIt) Information on the Federal Medication Terminologies may be found and downloaded from the NCI Web portal terminology resources page at www.cancer.gov/cancertopics/terminologyresources/FMT
Health Level Seven (HL7) Version 2.5/2.5.1	The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. Visit www.hl7.org for more information
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. Visit www.hl7.org for more information.

Standard	Description
Health Level Seven (HL7) Version 3.0	The HL7 Version 3.0 Messaging Standard is an application protocol for electronic data exchange in healthcare. Version 3.0 is based on a Reference Information Model (RIM); which is used to instantiate various message formats. Value sets / code tables are contained in the standard. Visit www.hl7.org for more information.
International Classification of Diseases, 9th Revision, Clinical Modifications (ICD-9-CM)	The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), Volumes I, II (diagnoses) and III (procedures) describes the classification of morbidity information for statistical purposes and for the indexing of healthcare records by diseases and procedures. Visit www.cdc.gov/nchs for more information
International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS)	The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS), describes the classification of inpatient procedures for statistical purposes and for the indexing of healthcare records by procedures. ICD-10-PCS is a procedural coding system managed by the Centers for Medicare and Medicaid Services (CMS). Visit www.cms.hhs.gov for more information
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 1.0	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called Integration Profiles) of established standards to deal with integration issues that cross providers, patient problems or time. The Cross Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile enables sharing of health information between enterprises of a regional health network, and further describes how to map content in a CDA medical document into registry metadata. In the registry, healthcare providers publish pointers to documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents. Visit www.ihe.net for more information.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev.3.0 for Final Text, specifies the IHE transactions defined and implemented as of December 9, 2006. The latest version of the IHE Technical Framework is available at www.ihe.net.
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. Visit www.loinc.org for more information
National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm	Provides standard names for (1) clinical drugs and (2) drug dose forms as administered to a patient. Also provides links from clinical drugs, both branded and generic, to their active ingredients, drug components (active ingredient + strength), and related brand names. Food and Drug Administration (FDA) National Drug Codes (NDCs) for specific drug products and many of the drug vocabularies commonly used in pharmacy management and drug interaction software are additionally linked to RxNorm. Visit www.nlm.nih.gov for more information
National Uniform Billing Committee (NUBC) Uniform Bill Version 1992 (UB-92) Current UB Data Specification Manual Field 22, Patient Discharge Status, Codes	A code set identifying status of patient discharge on an institutional claim (e.g., inpatient, outpatient, hospice, home care). Visit www.nubc.org for more information

Standard	Description
Unified Code for Units of Measure (UCUM) Expressions	A code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. Visit aurora.regenstrief.org for more information

3.0 TECHNICAL IMPLEMENTATION

3.1 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface, or code set has been implemented correctly.

3.1.1 CONFORMANCE CRITERIA

In order to claim conformance to this construct specification, an implementation must satisfy all the requirements and mandatory statements listed in this specification, the associated HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards.

Claims of conformance may only be made for the overall HITSP Interoperability Specification with which this construct is associated.

3.1.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification must be implemented in its entirety for an implementation to claim conformance to the specification. HITSP may define the permissibility for actor scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. Such scoping, subsetting and options may extend to associated constructs, such as this construct. This construct must implement all requirements within the selected scope, subset or options as defined in the associated Interoperability Specification to claim conformance.

4.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

Informative details regarding the contextual use of this construct:

NOTE: This construct must be reviewed in the context of the use case interoperability specification for dependencies and restrictions that may impose Anonymization and Pseudonymization privacy enhancement constraints and resulting construct dependencies on the information content.

5.0 CHANGE HISTORY

The following sections provide the history of all changes made to this document since the last publication.

No changes at this time.