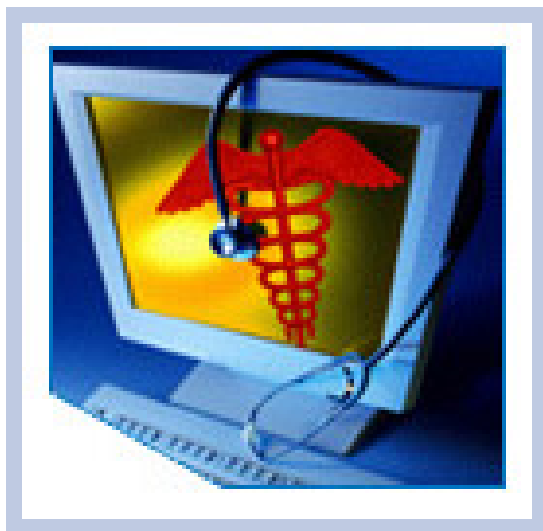


HITSP Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS) Component

HITSP/C38



Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Care Management and Health Records Domain Technical Committee



DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
0.0.1	Review Copy	Population Health Technical Committee	September 8, 2007
0.0.2	Review Copy	Population Health Technical Committee	December 5, 2007
1.0	Released for Implementation	Population Health Technical Committee	December 13, 2007
1.0.1	Review Copy	Care Management and Health Records Domain Technical Committee	August 20, 2008
1.1	Released for Implementation	Care Management and Health Records Domain Technical Committee	August 27, 2008



TABLE OF CONTENTS

1.0	INTRODUCTION	5
1.1	Overview	5
1.2	Component Document Map.....	5
1.3	Copyright Permissions.....	5
1.4	Reference Documents.....	6
2.0	COMPONENT DEFINITION.....	8
2.1	Context Overview	8
2.1.1	Component Constraints.....	8
2.1.2	Component Dependencies	8
2.2	Rules for Implementing.....	9
2.2.1	Data Mapping	9
2.2.1.1	Cross Reference Table Key	9
2.2.1.2	Patient Level Quality Data Message Data Set.....	10
2.2.1.3	Mapping Table.....	23
2.2.2	Guidelines and Examples.....	36
2.3	Standards	36
2.3.1	Regulatory Guidance.....	37
2.3.2	Selected Standards	37
2.3.3	Informative Reference Standards.....	39
3.0	TECHNICAL IMPLEMENTATION	40
3.1	Conformance	40
3.1.1	Conformance Criteria	40
3.1.2	Conformance Scoping, Subsetting and Options	40
4.0	APPENDIX	41
5.0	CHANGE HISTORY	42
5.1	December 5, 2007	42
5.2	December 13, 2007	42
5.3	August 20, 2008	42
5.4	August 27, 2008	42



FIGURES AND TABLES

Table 1.4-1 Reference Documents	6
Table 2.1.1-1 Component Constraints	8
Table 2.1.2-1 Component Dependencies	9
Table 2.2.1.1-1 Data Element Cross Reference	9
Table 2.2.1.2-1 Data Element Cross Reference	10
Table 2.2.1.2-2 Base Facility Data Elements	10
Table 2.2.1.2-3 Patient Data Elements	10
Table 2.2.1.2-4 Clinical Data Elements	12
Table 2.2.1.3-1 Patient Data Mapping	24
Table 2.2.1.3-2 Data Mapping	26
Table 2.3.1-1 Regulatory Guidance	37
Table 2.3.2-1 Selected Standards	37
Table 2.3.3-1 Informative Reference Standards	39



1.0 INTRODUCTION

As an introduction to the HITSP Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS) Component, this section provides a high level overview of 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 a list of 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 (HIE) prior to communicating the retrieved data described in this construct for analysis.

1.2 COMPONENT DOCUMENT MAP

Each HITSP specification describes how to integrate and constrain existing standards and specifications that will satisfy the requirements for the HITSP construct. There are four types of HITSP constructs called Interoperability Specifications (IS), Transaction Packages (TP), Transactions (T), and Components (C). Interoperability Specifications define the context(s) in which any other HITSP construct may be used. The current Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS) Component specification does not depend on any other HITSP constructs, however, it is used with other constructs to meet the requirements of one or more ISs. Review Section 1.2 Interoperability Specification Document Map from the relevant IS to better understand the context, dependencies, and relationships between the constructs used to meet the IS requirements.

1.3 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

© 2008 ANSI. This material may be copied without permission from ANSI only if and to the extent that the text is not altered in any fashion and ANSI's copyright is clearly noted.

Certain materials contained in this Interoperability Specification are reproduced from HL7 Version 2.5 and 3.0 with permission of Health Level Seven, Inc. No part of the material may be copied or reproduced in any form outside of the Interoperability Specification documents, including an electronic retrieval system, or made available on the Internet without the prior written permission of Health Level Seven, Inc. Copies



of standards included in this Interoperability Specification may be purchased from the Health Level Seven, Inc. Material drawn from these standards is credited where used.

IHE materials used in this document have been extracted from relevant copyrighted materials with permission of Integrating the Healthcare Enterprise (IHE) International. Copies of this standard may be retrieved from the IHE Web Site at www.ihe.net.

This material includes SNOMED Clinical Terms(r) (SNOMED CT(r)) which is used by permission of the International Health Terminology Standards Development Organisation (IHTSDO). All rights reserved. SNOMED CT(r) was originally created by The College of American Pathologists. "SNOMED" and "SNOMED CT" are registered trademarks of the IHTSDO

1.4 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from the www.hitsp.org Web Site.

Table 1.4-1 Reference Documents

Reference Document	Document Description
HITSP Interoperability Specification Overview	Provides 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.
HITSP Conventions List	Describes the conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
HITSP Harmonization Framework	Describes the current framework within which the Interoperability Specifications are built



Reference Document	Document Description
TN900 - Security and Privacy Technical Note	<p>Developed as a reference document to provide the overall context for use of the HITSP Security and Privacy constructs. It includes the following:</p> <ul style="list-style-type: none"> • The scope, reference policy background, and Security and Privacy principles used in the development of the constructs • A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs • A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases • A list of identified gaps and the recommended approaches to resolving those gaps • A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications • A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management • A glossary of terms used in all the Security and Privacy construct documents • A description of the application of the Security and Privacy constructs to the HITSP Interoperability Specifications for the three initial AHIC Use Cases – Biosurveillance, Electronic Health Records - Laboratory Results Reporting, and Consumer Empowerment <p>HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.</p>



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 HITSP Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS) Component constrains the IHE 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 Code	Constraint
No applicable constraints	

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			

2.2 RULES FOR IMPLEMENTING

The following section documents the content of the Component. It provides the basic 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 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 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.
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 Quality data and information requirements, the following provisional data dictionary was generated by the HITSP based upon interpretation of measure requirements provided by the HITEP. This list is currently under review by the NQF HITEP. Standards selected or under consideration by the HITSP team to constrain the vocabularies used for interoperability are provided.

Table 2.2.1.2-1 Data Element Cross Reference

Column	Definition
HITEP Data Element	Data element name/identifier as listed by the 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

HITEP(*)/Use Case Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
Facility Identifier	Facility Identifier	Unique facility identifier.	Numeric	CMS IDs	
Facility Name	Facility Name	Name of facility	String		
Facility Location	Facility Location	City and State	Coded	FIPS	Can be used for practice location

Table 2.2.1.2-3 Patient Data Elements

HITEP(*)/Use Case Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
Pseudonymized Data Linker	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	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)



HITEP(*)/Use Case Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
history-birth*	DOB	Date of birth	Date field	HL7 Timestamp HL7 V3 flavors of null for DOB	NOTE: May not be passing DOB for age over 89 due to HIPAA requirements
history-sex*	Sex	Patient sex	Coded	HL7 v 3 Administrative Gender M Male F Female UN Undifferentiated	
Visit data	Visit data	Electronic medical records billing codes		CPT Evaluation and Management Codes	
location-source/current/target*	Patient Class	General type of patient, <i>e.g.</i> , Inpatient, Outpatient, Emergency	Coded	HL7 2.5.5 Table 0004 Patient Class, ActEncounterCode subset of HL7 V3 ActCode, limited to IMP, AMB, EMER cooresponding to HL7 V2.X I,O,E	One of multiple data elements that can be leveraged to identify source/current/target
location-source/current/target*	Admission Source	This field indicates where the patient was admitted		Universal Billing codes (UB-04/NUBC CURRENT UB DATA SPECIFICATIONS MANUAL) UB-04 FL15	One of multiple data elements that can be leveraged to identify source/current/target
location-source/current/target*	Admission Type	This field indicates the circumstances under which the patient was or will be admitted	Coded	Universal Billing codes (UB-04/NUBC CURRENT UB DATA SPECIFICATIONS MANUAL) UB-04 FL14	One of multiple data elements that can be leveraged to identify source/current/target
Discharge Date/time	Discharge Date/time	Time of Inpatient discharge or release from ED	Date/time	HL7 Timestamp	
location-transfer type (AMA, routine)*	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-04/NUBC CURRENT UB DATA SPECIFICATIONS MANUAL) UB-04 FL17	Expected in Discharge (ADT^A03) transactions only



HITEP(*)/Use Case Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
history-death*	Deceased indicator	Indicator on record that the patient is deceased	Boolean	HL7 Table 0136Yes/No Indicator	
Deceased Date/time	Deceased Date/time	If patient has died, deceased date/time	Date/time	HL7 Timestamp	

Table 2.2.1.2-4 Clinical Data Elements

HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
Problem Data					
diagnosis-outpt (problem list)*; history-behavioral (smoker)*; history-enrollment trial*; history-symptoms*	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. NOTE: ICD-10 can be mapped (unidirectional) Reason for admission is not a separate data element on this list but could be reflected as a problem		SNOMED CT ICD9-CM	HL7 Definition Chapter 12: A problem of a given individual can be described by formal diagnosis coding systems (such as DRGs, nursing terminologies, ICD9-CM, DSM, etc.) or by other professional descriptions of healthcare issues affecting an individual. Problems can be short- or long-term in nature, chronic or acute, and have a status. In a longitudinal record, all problems may be of importance in the overall 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
problem list*; history-behavioral (smoker)*; history-enrollment trial*; history-symptoms*	Problem Date	This is the range of time of which the problem was active for the patient	Timestamp		
problem list*; history-behavioral (smoker)*; history-enrollment trial*; history-symptoms*	Problem Type	This is a fixed value indicating the level of medical judgment used to determine the existence of a problem	Coded		



HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
problem list*; history-behavioral (smoker)*; history-enrollment trial*; history-symptoms*	Problem Name	This is a text description of the problem suffered	Text		
problem list*; history-behavioral (smoker)*; history-enrollment trial*; history-symptoms*	Problem Code	This value is a code describing the problem according to a specific vocabulary of problems	Coded		
adverse_drug_event-allergy*	Allergies	Allergies/adverse reactions only related to medications or food substances	CE (coded)	CHI Allergy Recommendation (HL7 Allergen type code /Allergen reaction code – use SNOMED CT code here/ and need coded value for Allergen (UNII – Unique Ingredient Identifier derived from FDA SRS and EPA Substance Registry System for non-drug chemicals, RXNORM – including brand-name, NDF-RT – to drug class rather than brand name), SNOMED CT for allergy type, severity, reaction	NOTE: Assumption – allergies/adverse reactions only related to medications
adverse_drug_event-intolerance*	Substance Intolerance	Actual or anticipated side effects that may represent exclusions for measures	CE (coded)	SNOMED CT ICD9-CM	NOTE: ICD-10 can be mapped (unidirectional)
Adverse Event Entry					
Adverse Event Data	Adverse Event Date	This is a date that expresses when this particular allergy or intolerance was known to be active for the patient	Timestamp	HL7 Timestamp	



HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
Adverse Event Data	Adverse Event Type	Describes the type of product and intolerance suffered by the patient. The type of product shall be classified with respect to whether the adverse event occurs in relationship with a medication, food, or environmental or other product. The adverse event should also be classified more specifically as an allergy, non-allergy intolerance, or just adverse reaction if that level of detail is not known	Coded	SNOMED CT Preferred Terms for Adverse Event Type	
Product in Support of Adverse Event Data					
Adverse Event Data	Product Free-Text	This is the name or other description of the product or agent that causes the intolerance	Text		
Adverse Event Data	Product Coded	This value is a code describing the product	Coded		
Reaction in Support of Adverse Event Data					
Adverse Event Data	Reaction Free-Text	This is the reaction that may be caused by the product or agent	Text		
Adverse Event Data	Reaction Coded	This value is a code describing the reaction	Coded		
Severity in Support of Adverse Event Data					
Adverse Event Data	Severity Free-Text	This is a description of the level of severity of the allergy or intolerance	Text		
Adverse Event Data	Severity Coded	This value is a code describing the level severity of the allergy or intolerance	Coded	SNOMED CT Preferred Terms for Severity	



HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
Diagnosis Data					
diagnosis-inpt (admission/discharge)*; diagnosis-outpt (billing)*	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)	CE (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 National Library of Medicine (NLM) and vendor community (NOTE: ICD-10 can be mapped (unidirectional)). Further validation will be done by AHIMA
Diagnosis Type	Diagnosis Type	Type of diagnosis being sent (admitting, working, final)	IS (coded)	HL7 2.5 User-defined Table 0052 - Diagnosis Type For CDA, It can be derived from the section code For Vocabulary, use section code (LOINC)	
Diagnosis Priority	Diagnosis Priority	Data element used to indicate Principal diagnosis in message	ID (coded)	HL7 Table 0359 – Diagnosis Priority	
Vital Signs					
physical exam-vitals*	Blood Pressure – Diastolic Observation Date/Time	Systolic/Diastolic blood pressure measurement and the date/time that it was performed	NM/SN (Numeric or Structured Numeric)	LOINC for observation identifier, UCUM Blood Pressure Unit Code	
physical exam-vitals*	Blood Pressure – Systolic Observation Date/Time	Systolic/Diastolic blood pressure measurement and the date/time that it was performed	NM/SN (Numeric or Structured Numeric)	LOINC for observation identifier, UCUM Blood Pressure Unit Code	
physical exam-vitals*	Pulse Oximetry Observation Date/Time	Pulse oximetry reading and the date/time that it was performed	NM/SN (Numeric or Structured Numeric)	LOINC for observation identifier	NOTE: in addition to the HITEP data element type list



HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
Procedures and Diagnostic Tests					
diagnostic study-ordered*; procedure-ordered (consult)*; laboratory-order*	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	CE (Coded)	SNOMED CT, LOINC/DICOM, CPT Category II ¹	Possible Gap in reconciling data with workflow 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 NOTE: this is subject to harmonization of terms across HITSP TCs 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-inpatient (end/closure)*; procedure-inpatient (start/incision)*; procedure-outpatient*; procedure-past procedure history (pacer)*	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	CE (Coded)	CPT-4, ICD-9, SNOMED CT	NOTE: ICD-10 can be mapped (unidirectional)

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.



HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
Provider Identifier	Provider Identifier	Unique provider (clinician) identifier		NPI	Need clarification from HITEP regarding provider-patient relationship (e.g. attending, admitting, PCP, consultant) required for attribution. The provider roles are provided as reference but require resolution of GAP for full implementation GAP: Business rule applied to the attribution needs to be defined
history-primary care provider*	Provider Role	Function or responsibility assumed by a provider in the context of a healthcare event. Role information documents a person's association with an identified healthcare activity. Examples include primary care provider, transcriptionist, reviewer, and consulting physician			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					
communication-provider-pt (instructions, counseling)*	Documentation of communication: provider to patient	Documentation of communication: provider to patient (paper or verbal) e.g., discharge instructions		SNOMED CT LOINC	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
communication-provider-provider (consult)*	Documentation of communication: provider to provider	Consult between clinicians (e.g. an eye exam with appropriate components)		Consultation note coded in SNOMED CT	Likely to be text in existing systems, some may be codified in nursing terminologies which can be mapped to SNOMED



HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
history-care classification (CMO, DNR/I, pal care)*	Care Classification	Care classification of comfort measures only, DNR, or DNI (e.g. palliative care)		Consultation note coded in SNOMED CT	(See SNOMED CT Procedure 133918004)385897008 – Care Regimes Management GAP: "Comfort level only" is inconsistently defined and applied, requires standardization for equal application of measures and exclusion criteria. Referred to HITEP
Medication Data					
medication-inpatient order ("on discharge"); medication-outpatient order*	Medication Ordered	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; immunizations and therapy should be expressed as clinical vaccine formulation (CVX)	CE (Coded)	Federal Medication Terminologies, CVX, CPT	Prefer RxNORM, NDF-RT, and CVX for Immunizations; CPT codes should be mapped to CVX codes; Where CVX codes do not exist and there is a CPT code, CPT codes may be used. NOTE Gap in the completeness of the CPT/CVX mapping – refer to terminology developers. Overlap in the terminology and update schedules. NOTE: timeliness is less of an issue for quality measures than for clinical decision support – Roadmap request to resolve gap/overlap



HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
Medication-discontinue order*	Order Control (message-based)	This element relates to a measure expecting antibiotics to stop within 24 hours after the end of surgery. If continued past 24 hours without cause, this may increase resistance/complications	CE (Coded)	V3 HL7TriggerEventCode	Review with HITEP whether this is sufficient Can support Medication discontinue order: GAP in process: Referral to HITEP: Can or should measures add other ways of determining a short duration of medication for appropriate measure definition? process gap to reflect the discontinuation efficiently; the intent of continuing medications for no more than 24 hrs after procedure can be met without writing a discontinue. The intent might also be met by an exact number of medications written post-op with appropriate frequency, so discontinue order as a data element might not be needed
Medication-discontinue order*	Indicate Medication Stopped (Document-based)	This element relates to a measure expecting antibiotics to stop within 24 hours after the end of surgery. If continued past 24 hours without cause, this may increase resistance/complications	TS (Timestamp)		GAP in process: Referral to HITEP: Can or should measures add other ways of determining a short duration of medication for appropriate measure definition? process gap to reflect the discontinuation efficiently; the intent of continuing medications for no more than 24 hrs after procedure can be met without writing a discontinue. The intent might also be met by an exact number of medications written post-op with appropriate frequency, so discontinue order as a data element might not be needed



HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
Authorizing provider	Authorizing provider	Medication prescriber/orderer	XCN (Extended Coded Name)	NPI	
Medication-inpatient administered (first, last, route)*	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	CE (Coded)	RxNorm	NOTE: This data element is expected to be harmonized with the output of the HITSP medication management efforts
Medication-inpatient administered (first, last, route)*	Medication administered Route	Route of medication administration	CE (Coded)	RxNorm	May use HL7 Table 0162 Route of Administration
Medication-inpatient administered (first, last, route)*	Medication administration date/time	Date/time that medication was administered in a controlled setting such as ED, ambulatory surgical centers, inpatient	TS (Timestamp)	HL7 Timestamp	NOTE: This data element is expected to be harmonized with the output of the HITSP medication management efforts
medication-outpatient duration	Number of doses prescribed (quantity ordered)	Used to determine whether patient received the number of days of therapy needed to meet the quality criteria	Numeric		outpatient duration is a derived data element to be derived from number of doses prescribed and dose frequency, order expiration date/time
medication-outpatient duration	Dose frequency	Ordered daily frequency of the medication	CE (Coded)		outpatient duration is a derived data element to be derived from number of doses prescribed and dose frequency, order expiration date/time NOTE: Gap – we have selected a user defined table; Refer to HL7 and NCPDP identify a standard coded value set for this concept
medication-outpatient duration	Refills	This field defines the number of times the requested dispense amount can be given to the patient, subject to local regulation. Refers to outpatient only	Numeric		Could be used to compute days supplied for the entire order Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ



**HITSP Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)
Component**

Released for Implementation
20080827 V1.1

HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
medication-outpatient duration	Days Supplied (message-based)	This field specifies the quantity dispensed on the original fill (first fill) of a prescription when that amount is not the same as the quantity to be used in refills	Numeric		Gap: Outpatient duration – not available in wide enough implementation to expect this will be sufficient Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ
medication-outpatient duration	Order expiration date/time (document-based)	The date, including time if applicable, when the order is no longer valid. Dispenses and administrations are not continued past this date for an order instance	TS (Timestamp)		Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ
medication-outpatient duration	Fulfillment history (document-based)	History of dispenses for this order. Comprised of Fulfillment History Components	Loops of PVD (Prescriber), PVD (Pharmacy) and DRU (Drug) Segments to relay up to 300 history occurrences, within Medication History Response mapped to CDA		Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ
medication-outpatient duration	Dispense Date (document-based)	Fulfillment History Component: The date of this dispense	TS (Timestamp)		Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ
medication-outpatient duration	Quantity Dispensed (document-based)	Fulfillment History Component: The actual quantity of product supplied in this dispense. Note: this is comprised of both a numeric value and a unit of measure	Numeric, Unit of measure		Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ



HITSP Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS) Component

Released for Implementation
20080827 V1.1

HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
medication-outpatient duration	Fill number (document-based)	Fulfillment History Component: The fill number for the history entry. Identifies this dispense as a distinct event of the prescription	Numeric		Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ
medication-outpatient duration	Fill status (document-based)	Fulfillment History Component. The fill event status is typically "complete" indication the fill event has been, or is expected to be picked up. A status of "aborted" indicates that the dispense was never picked up (e.g., "returned to stock")	CE (Coded)	HL7 V3 ActStatusNormal Vocabulary	Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ
Derived attributes (e.g. continuous use say of beta blockers over 6 months)	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
Study Findings/Test Results - Laboratory					
laboratory-order*	Resulted test	The identifier code for the specific test component resulted	CE (Coded)	LOINC Laboratory Test Identifiers include analytes, specimen source, methods, and sensitivity tests for drugs	
laboratory-result*	Result value	Laboratory test results including susceptibilities, serologies, non-organisms; coded value	SN or NM (Numeric) or CE (Coded)	SNOMED-CT (non-numeric laboratory such as organisms and other coded results)	
laboratory-result*	Result unit	Units for numeric result context	CE (Coded)	Unified Code for Units of Measure (UCUM) Expressions	GAP: Units may be text data currently
Report date/time	Report date/time	Laboratory microbiology result date/time	TS (Timestamp)	HL7 Timestamp	



**HITSP Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)
Component**

Released for Implementation
20080827 V1.1

HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
Result status	Result status	Status of report (preliminary, final, corrected)	ID (Coded)	HL70123 Result Status	
laboratory-result*	Test interpretation	Interpretation of test result by the laboratory, including the susceptibility test interpretation	IS (Coded)	HL70078 Abnormal Flags	
Study Findings/Test Results – Radiology and Other Studies					
diagnostic study-ordered*; procedure-ordered (consult)*;	Test Performed	Radiology and other diagnostic test information (e.g. radiology findings, echocardiogram results, LVEF)	CE (Coded)	CPT+ Textual Description which can include modification	
Report date/time	Report date/time	Report/Reading Date. This date is updated with report corrections and addenda	TS (Timestamp)	HL7 Timestamp	
Result status	Result status	Status of report (preliminary, final, corrected)	ID (Coded)	HL70123 Result Status	
diagnostic study-result (EKG, LVEF, radiology)*	Result value	Study findings exclusive of laboratory (e.g., radiology findings, echocardiogram LVEF)	SN or NM (Numeric) or CE (Coded)	DICOM (structured report), SNOMED-CT ICD9-CM/ICD-10, CPT Category II	
diagnostic study-result (EKG, LVEF, radiology)*	Impressions	Interpretation of study, by provider of service including diagnosis and impressions	CE (Coded)	DICOM (structured report), SNOMED CT Or ICD9-CM	Most likely text (alphanumeric) NOTE: ICD-10 can be mapped (unidirectional)

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 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	A unique, randomly generated, encoded number that links to patient-level information (i.e., name and 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 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 HL7 V3 flavors of null for DOB		ClinicalDocument/recordTarget/patientRole/patient/birthTime	
Sex	Patient sex/gender	HL7 V3Administrative Gender(coded) M Male F Female UN Undifferentiated		ClinicalDocument/recordTarget/patientRole/patient/administrativeGenderCode	
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	
Admission Source	This field indicates where the patient was admitted	Universal Billing codes (UB-04/NUBC) Current UB Data Specifications Manual: FL20 "Source of Admission" passed as HL7 IS (user defined codes) datatype		/ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility	V3 has "encounterAdmissionSource" but it only has Emergency, L&D, Newborn



Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/ Pre-conditions
Admission Type	This field indicates the circumstances under which the patient was or will be admitted	Universal Billing codes (UB-04/NUBC CURRENT UB DATA SPECIFICATION S MANUAL): "Type of Admission" passed as HL7 IS (user defined codes) datatype		/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 the 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 standards claims-based codes	Universal Billing codes (UB-04/NUBC CURRENT UB DATA SPECIFICATION S 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/	



Table 2.2.1.3-2 Data Mapping

Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
Problem Data					
Problems	<p>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</p> <p>While we recognize that ICD9-CM is currently used in many systems, evolution toward SNOMED is preferred</p> <p>Reason for admission is not a separate data element on this list but could be reflected as a problem</p>	<p>SNOMED CT</p> <p>ICD9-CM</p>		<p>ClinicalDocument/component/structuredBody/component/section code/@code="PROBLEMS LIST 11450-4" /entry/observation</p>	<p>HL7 Definition Chapter 12: A problem of a given individual can be described by formal diagnosis coding systems (such as DRGs, NANDA Nursing Diagnosis, ICD9, DSM, etc.) or by other professional descriptions of healthcare issues affecting an individual. Problems can be short- or long-term in nature, chronic or acute, and have a status. In a longitudinal record, all problems may be of importance in the overall 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</p>
Problem Entry				<p>ClinicalDocument/component/structuredBody//cda:act[cda:templateId/@root='2.16.840.1.113883.10.20.1.27']/cda:entryRelationship[@typeCode='SU BJ']/cda:observation[cda:templateId/@root='2.16.840.1.113883.10.20.1.28']</p>	
Problem Date	This is the range of time which the problem was active for the patient	Timestamp		<p>ClinicalDocument/component/structuredBody//cda:act[cda:templateId/@root='2.16.840.1.113883.10.20.1.27']/cda:entryRelationship[@typeCode='SU BJ']/cda:observation[cda:templateId/@root='2.16.840.1.113883.10.20.1.28'] /cda:effectiveTime cda:effectiveTime</p>	



Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
Problem Type	This is a fixed value indicating the level of medical judgment used to determine the existence of a problem	Coded		ClinicalDocument/component/structuredBody/cda:act[cda:templateId/@root='2.16.840.1.113883.10.20.1.27']/cda:entryRelationship[@typeCode='SU BJ']/cda:observation[cda:templateId/@root='2.16.840.1.113883.10.20.1.28']/cda:code	
Problem Name	This is a text description of the problem suffered	Text		ClinicalDocument/component/structuredBody/cda:act[cda:templateId/@root='2.16.840.1.113883.10.20.1.27']/cda:entryRelationship[@typeCode='SU BJ']/cda:observation[cda:templateId/@root='2.16.840.1.113883.10.20.1.28']/cda:text	
Problem Code	This value is a code describing the problem according to a specific vocabulary of problems	Coded		ClinicalDocument/component/structuredBody/cda:act[cda:templateId/@root='2.16.840.1.113883.10.20.1.27']/cda:entryRelationship[@typeCode='SU BJ']/cda:observation[cda:templateId/@root='2.16.840.1.113883.10.20.1.28']/cda:value	
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 represent exclusions for measures	SNOMED CT ICD-9, CE (coded)		ClinicalDocument/component/structuredBody/component/section/code/@code="Allergies, Adverse Reactions, Alerts 48765-2"	
Adverse Event Entry				ClinicalDocument/component/structuredBody/cda:act[cda:templateId/@root='2.16.840.1.113883.10.20.1.27']/cda:entryRelationship[@typeCode='SU BJ']/cda:observation[cda:templateId/@root='2.16.840.1.113883.10.20.1.18']	
Adverse Event Date	This is a date that expresses when this particular allergy or intolerance was known to be active for the patient	Timestamp		ClinicalDocument/component/structuredBody/cda:act[cda:templateId/@root='2.16.840.1.113883.10.20.1.27']/cda:entryRelationship[@typeCode='SU BJ']/cda:observation[cda:templateId/@root='2.16.840.1.113883.10.20.1.18']/cda:effectiveTime	



Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
Adverse Event Type	Describes the type of product and intolerance suffered by the patient. The type of product shall be classified with respect to whether the adverse event occurs in relationship with a medication, food, or environmental or other product. The adverse event should also be classified more specifically as an allergy, non-allergy intolerance, or just adverse reaction if that level of detail is not known	SNOMED CT Preferred Terms for Adverse Event Type		ClinicalDocument/component/structuredBody//cda:act[cda:templateId/@root='2.16.840.1.113883.10.20.1.27']/cda:entryRelationship[@typeCode='SUBJ']/cda:observation[cda:templateId/@root='2.16.840.1.113883.10.20.1.18']/cda:code	
Product				cda:participant[@typeCode='CSM']/cda:participantRole[@classCode='MANU']/cda:playingEntity[@classCode='MMAT']	
Product-Free Text	This is the name or other description of the product or agent that causes the intolerance			cda:name	
Product Coded	This value is a code describing the product			cda:code	
Reaction				ClinicalDocument/component/structuredBody//cda:entryRelationship[@typeCode='MFST']/cda:observation[templateId/@root='2.16.840.1.113883.10.20.1.54']	
Reaction Free-Text	This is the reaction that may be caused by the product or agent			cda:text cda:text	
Reaction Coded	This value is a code describing the reaction			cda:value	
Severity				ClinicalDocument/component/structuredBody//cda:entryRelationship[@typeCode='SUBJ']/cda:observation[templateId/@root='2.16.840.1.113883.10.20.1.55']	
Severity Free-Text	This is a description of the level of severity of the allergy or intolerance			ClinicalDocument/component/structuredBody//cda:entryRelationship[@typeCode='SUBJ']/cda:observation[templateId/@root='2.16.840.1.113883.10.20.1.55']/cda:text	



Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
Severity Coded	This value is a code describing the level severity of the allergy or intolerance.	SNOMED CT Preferred Terms for Severity		ClinicalDocument/component/structuredBody/cda:entryRelationship[@typeCode='SUBJ']/cda:observation[templateId/@root='2.16.840.1.113883.1.0.20.1.55']/cda:value	
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/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
Diagnosis Type	Type of diagnosis being sent (admitting, working, final)			ClinicalDocument/component/structuredBody/component/section/code	
Diagnosis Priority	Data element used to indicate Principal diagnosis in message			/ClinicalDocument/component/structuredBody/component/section/entry/observation/interpretationCode/@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 HITSP data element type list



**HITSP Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)
Component**

Released for Implementation
20080827 V1.1

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 TCs 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 (See PIX/PDQ)		ClinicalDocument/componentOf/encapsulatingEncounter/encounterParticipant/assignedEntity/ID	Need clarification from HITEP regarding provider-patient relationship (e.g. attending, admitting, PCP, consultant) required for attribution. The provider roles are provided as reference but require resolution of GAP for full implementation GAP: Business rule applied to the attribution needs to be defined
Provider Role	Function or responsibility assumed by a provider in the context of a healthcare event. Role information documents a person's association with an identified healthcare activity. Examples include primary care provider, transcriptionist, reviewer, and consulting physician	TBD – See Overlap		ClinicalDocument/componentOf/encapsulatingEncounter/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



HITSP Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS) Component

Released for Implementation
20080827 V1.1

Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
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, LOINC		ClinicalDocument/component/structuredBody/component/section code/@code="Hospital Discharge Instructions 8653-8"	Likely to be text in existing systems, some may be codified 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 Error! Bookmark not defined.		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 the procedure section for procedure occurrence and 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		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, requires standardization for equal application of measures and exclusion criteria Referred to HITEP
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



Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
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
Number of doses prescribed (quantity ordered)	Used to determine whether patient received the number of days of therapy needed to meet the quality criteria	Numeric		ClinicalDocument/component/structuredBody/cda:substanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.1.24']/cda:entryRelationship[@typeCode='REFR']/cda:supply[moodCode='INT']/cda:quantity	Outpatient duration is a derived data element to be derived from number of doses prescribed and dose frequency
Dose frequency	Ordered daily frequency of the medication	CE (Coded)		ClinicalDocument/component/structuredBody/cda:substanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.1.24']/cda:effectiveTime[2]	Outpatient duration is a derived data element to be derived from number of doses prescribed and dose frequency NOTE: Gap – we have selected a user defined table; Refer to HL7 and NCPDP identify a standard coded value set for this concept
Refills	This field defines the number of times the requested dispense amount can be given to the patient, subject to local regulation. Refers to outpatient only			ClinicalDocument/component/structuredBody/cda:substanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.1.24']/cda:entryRelationship[@typeCode='REFR']/cda:supply[moodCode='INT']/cda:repeatNumber	Could be used to compute applied for the entire order



Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
Days Supplied	This field specifies the quantity dispensed on the original fill (first fill) of a prescription when that amount is not the same as the quantity to be used in refills	Numeric		NA (message-based concept)	Gap: Outpatient duration – not available in wide enough implementation to expect this will be sufficient
Order expiration date/time	The date, including time if applicable, when the order is no longer valid. Dispenses and administrations are not continued past this date for an order instance	Timestamp		ClinicalDocument/component/structuredBody//cda:entryRelationship[@typeCode='REFR']/ cda:supply[moodCode='INT']/ cda:effectiveTime/cda:high	Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ
Fulfillment history	History of dispenses for this order. Comprised of Fulfillment History Components	Loops of PVD (Prescriber), PVD (Pharmacy) and DRU (Drug) Segments to relay up to 300 history occurrences, within Medication History Response mapped to CDA		ClinicalDocument/component/structuredBody//cda:supply[@moodCode='EVN']	Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ
Dispense Date	Fulfillment History Component: The date of this dispense	Timestamp		ClinicalDocument/component/structuredBody//cda:supply[@moodCode='EVN']/cda:effectiveTime	Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ.
Quantity Dispensed	Fulfillment History Component: The actual quantity of product supplied in this dispense. Note: this is comprised of both a numeric value and a unit of measure	Numeric, Unit of measure		ClinicalDocument/component/structuredBody//cda:supply[@moodCode='EVN']/cda:quantity	Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ
Fill Number	Fulfillment History Component: The fill number for the history entry. Identifies this dispense as a distinct event of the prescription	Numeric		ClinicalDocument/component/structuredBody//cda:supply[@moodCode='EVN'].. cda:sequenceNum	Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ



Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
Fill Status	Fulfillment History Component. The fill event status is typically „complete“ indicating the fill event has been, or is expected to be picked up. A status of „aborted“ indicates that the dispense was never picked up (e.g., “returned to stock”)	CE (Coded)	HL7 ActStatusNormal Vocabulary	ClinicalDocument/component/structuredBody/cda:supply[@moodCode=‘EVN’]/cda:statusCode	Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ
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
Study Findings/Test Results – Laboratory					
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	



Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
Result value	Laboratory test results including susceptibilities, serologies, non-organisms; coded value	SNOMED-CT (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	Laboratory microbiology result date/time	HL7 Timestamp, TS (Timestamp)		ClinicalDocument/component/structuredBody/component/section/entry/observation/effectiveTime	
Result status	Status of report (preliminary, final, corrected)	HL7 V3 ActStatus		ClinicalDocument/component/structuredBody/component/section/entry/observation/statusCode	
Test interpretation	Interpretation of test result by the laboratory, including the susceptibility test interpretation	HL7 V3 Observation interpretation		ClinicalDocument/component/structuredBody/component/section/entry/observation/interpretationCode	
Study Findings/Test Results – Radiology and Other Studies					
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)	HL7 V3 ActStatus		ClinicalDocument/component/structuredBody/component/section code/@code="Studies Summary 30954-2" entry/observation/statusCode)	



Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
Result value	Study findings exclusive of laboratory (e.g., radiology findings, echocardiogram LVEF)	DICOM (structured report), SNOMED-CT ICD9-CM/ICD-10, CPT Category II		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 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 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 standards used by this Component specification fall into the following categories:

- Regulatory guidance is a legal or other authoritative declaration that HITSP must abide by in standards selection (see Section 2.3.1)
- Selected standards are necessary for interoperability. These are standards that are used to meet information exchange requirements of associated constructs. For example, they are used to realize direct information exchange, to provide the transport mechanism, to specify the content, or to address security (see Section 2.3.2)
- Informative reference standards provide additional background information or guidance, and are not required for interoperability. These standards are not required to implement the Component specification (see Section 2.3.3)



2.3.1 REGULATORY GUIDANCE

The following table provides a list of legal or other authoritative guidelines that HITSP must abide by, or has agreed to use as guidance in the selection of standards. Note that only the referenced sections of the regulations are relevant to this Component specification.

Table 2.3.1-1 Regulatory Guidance

Standard	Description
No applicable regulatory guidance	

2.3.2 SELECTED STANDARDS

The following table provides a list of standards that are used to meet information exchange requirements of the Component specification, and a detailed description of each standard.

Table 2.3.2-1 Selected Standards

Standard	Description
American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4); CPT Evaluation and Management Codes	A uniform coding system used primarily to identify medical services and procedures furnished by physicians and other healthcare professionals. For more information visit www.ama-assn.org
Centers for Medicare and Medicaid Services (CMS) National Provider Identifier (NPI)	NPI is a unique 10-digit identification number issued to healthcare 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 healthcare 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. For more information visit www.cms.gov
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. For more information visit www.itl.nist.gov 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



Standard	Description
Federal Medication Terminologies	<p>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)</p> <p>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)</p> <p>Information on the Federal Medication Terminologies may be found and downloaded from the NCI Web portal terminology resources page at www.cancer.gov/cancertopics</p>
Health Level Seven (HL7) Version 2.5	<p>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</p>
Health Level Seven (HL7) Version 3.0	<p>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</p>
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 3.0, 2007 - 2008, Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile	<p>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. For more information visit www.ihe.net</p>
International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS)	<p>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). For more information visit www.cms.hhs.gov</p> <p>Note: While ICD-10 is not deployed in US installations, we recognize the need to move toward new releases of coded values.</p>
International Classification of Diseases, 9th Revision, Clinical Modifications (ICD-9-CM)	<p>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. For more information visit www.cdc.gov/nchs</p>



HITSP Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS) Component

Released for Implementation
20080827 V1.1

Standard	Description
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	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. For more information visit www.ihtsdo.com
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. RxNorm is a part of the Federal Medication Terminologies. For more information visit www.nlm.nih.gov
National Uniform Billing Committee (NUBC) Uniform Bill Version 2007 (UB-04) 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). For more information visit www.nubc.org
Unified Code for Units of Measure (UCUM)	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. For more information visit http://aurora.regenstrief.org

2.3.3 INFORMATIVE REFERENCE STANDARDS

The following table lists standards that provide additional background information or guidance; however, they are not required for the implementation of the Component specification.

Table 2.3.3-1 Informative Reference Standards

Standard Name	Description/Reason for Use
No applicable informative reference standards	



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. A conformant system must also be constrained as specified in table 2.1.1-1, and implement all of the required actors, where defined, within the scope, subset or implementation option that is selected from the associated Interoperability Specification.

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.

No additional information at this time.



5.0 CHANGE HISTORY

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

5.1 DECEMBER 5, 2007

- Added mapping to HITEP-identified data elements or TC-identified elements to support the HITSP Use Case
- Added data elements to round out concepts for problems, medications, and adverse events and to align with HITSP/C32
- Updated vocabularies to use V3 vocabulary sets as should be done for V3 CDA

5.2 DECEMBER 13, 2007

Upon approval by the HITSP Panel on December 13, 2007, this document is now Released for Implementation.

5.3 AUGUST 20, 2008

This document has been modified to reflect the updated HITSP approach to categorizing standards as Regulatory Guidance, Selected Standards, and Informative References.

Deleted the following from the standards listing:

- Consolidated Health Informatics (CHI)
- Digital Imaging and Communications in Medicine (DICOM) Attribute Level Confidentiality Supplement: # 55

Added the following Selected Standard:

- Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 3.0, 2007 - 2008, Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile

5.4 AUGUST 27, 2008

Upon approval by the HITSP Panel on August 27, 2008, this document is now Released for Implementation.

