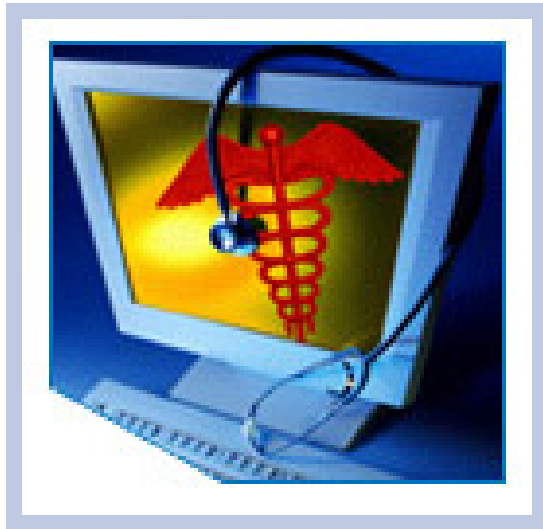


# HITSP Quality Interoperability Specification

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HITSP/IS06



*Submitted to:*

**Healthcare Information Technology Standards Panel**

*Submitted by:*

**Population Perspective Technical Committee  
(Formerly Population Health Technical Committee)**



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## 1.0 INTRODUCTION

As an introduction to the HITSP Quality Interoperability Specification, 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 the Interoperability 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 Interoperability Requirements.

### 1.1 INTEROPERABILITY SPECIFICATION OVERVIEW

This section provides a high level definition of this Interoperability Specification and background information about the underlying Use Case that it is based upon. This Quality Interoperability Specification is designed to enable interoperable, electronic quality (eQuality) monitoring. This process provides implementers with a set of standards and workflows to enable that eQuality monitoring. Specifically, it provides selected standards for encoding the data types required for encoding an electronic quality measure. In this release of the Interoperability Specification, we provide the standards required to support the encoding of the initial set of quality measures selected by the Health Technology Expert Panel (HITEP). The intent is to provide a method to encode clinical data obtained during the routine practice of medicine that would then be available to match against the encoded quality measure to determine if the patient or population of patients met any of these specified quality criteria. In so doing, our hope is that we can provide feedback to clinicians, administrators, policy makers and public health authorities for the purpose of improving the quality of healthcare provided to U.S. patients.

This Quality Interoperability Specification is based on a Use Case that assumes the presence of Electronic Health Records (EHRs) within the healthcare delivery system and promotes the development of longer-term efforts.

The Use Case models the exchange of information between the EHR and quality measurement, feedback and reporting systems. The Use Case allows for a hybrid model of data collection, where claims and or manual data collection will be required to support certain measures that are not supported through EHRs. This Use Case acknowledges the need to include a combination of claims and clinical (e.g., EHR) data. With more automation, EHR data could be extracted for patients to provide a richer measure set. However, the Use Case acknowledges that manual review and processing will continue to be required in many contexts and settings.

This Use Case does not attempt to prescribe a definitive approach to the location of data aggregation. The Use Case does describe roles for these processes which may be fulfilled in several different settings. The Use Case also does not describe harmonized quality measures. Separate American Healthcare Information Community (AHIC) processes will determine the initial and subsequent quality measures to be used. The data flows indicated are not intended to be comprehensive or limiting.



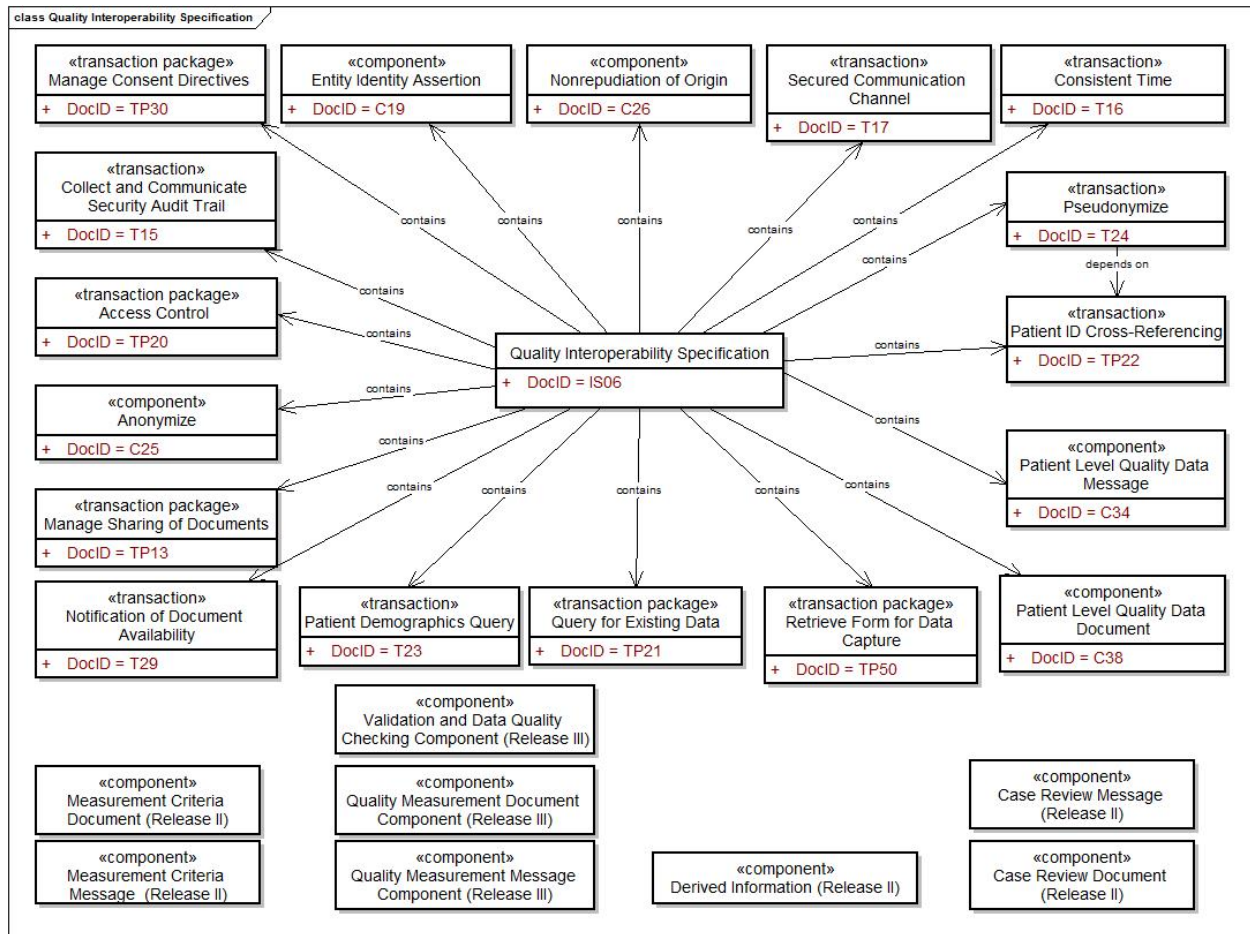
The Interoperability Specification is created to be architecture neutral. Patient level data analysis and aggregation may occur at the local care delivery locations, at an intermediate site, or at the location of the receiver of patient level quality data. It is expected that implementations will use the standards identified to accommodate any of these site-specific architecture requirements.

## **1.2 INTEROPERABILITY SPECIFICATION DOCUMENT MAP**

Each HITSP Interoperability Specification (IS) is comprised of a suite of constructs that, taken as a whole, define how to integrate and constrain existing standards and specifications to satisfy the requirements imposed by a given Use Case. The IS groups specific actions and actors to describe the relevant context(s) for the use of HITSP constructs that further identify and constrain standards where necessary. In addition to ISs, there are three other types of HITSP constructs called Transaction Packages (TP), Transactions (T), and Components (C). The roadmap depicted in Figure 1.2-1 identifies the HITSP constructs used to meet the IS requirements. Implementers should read the documents that describe the constructs depicted in the diagram for their details and specific uses.



**Figure 1.2-1 Interoperability Specification Document Map**



### 1.2.1 LIST OF CONSTRUCTS

The following table lists and describes the HITSP constructs that are shown in the Unified Modeling Language (UML) diagram above and are used by the Interoperability Specification. All references to HITSP specifications are to the current, and Panel approved 'Released for Implementation' versions of the specifications.

The HITSP Quality Interoperability Specification leverages existing HITSP constructs for document sharing and also supports message-based communications. New constructs reflect additional document communication options (e.g. media and email), and identify several Components for communication of the various Use Case information payloads. These Components support both message-based and document-based communications.





**Table 1.2.1-1 List of Constructs**

New Construct	Construct Description
HITSP/TP21- Query for Existing Data	Transaction Package supporting retrieval of patient level quality data from source repositories to compile the required patient level data submission
HITSP/C34 - Patient Level Quality Data Message	Component supporting the message-based communication of patient level quality data
HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	Component supporting the document-based communication of patient level quality data
HITSP/TP13 - Manage Sharing of Documents	<p>To support "Manage Sharing of Documents" HITSP is using the Cross-Enterprise Document Sharing Integrating the Healthcare Enterprise (IHE) Integration Profile, which facilitates the registration, distribution and access of patient electronic health records across health enterprises. The Cross-Enterprise Document Sharing (XDS) Profile is focused on providing a standards-based specification for managing the sharing of documents between any healthcare enterprises, ranging from a private physician office to a clinic to an acute care in-patient facility</p> <p>This specification includes by reference the Transactions and Components that comprise HITSP/TP13 - Manage Sharing of Documents. It describes the processes supported by these structures and the work that is accomplished by implementing this Transaction Package. Source material was from the IHE IT Infrastructure (ITI) Technical Framework (TF) Cross-Enterprise Document Sharing (XDS) profile.</p> <p>(Including Document Integrity - to ensure the integrity of a document that is exchanged or shared)</p>
HITSP/T23 - Patient Demographics Query	HITSP Patient Demographics Query Transaction
HITSP/T29 - Notification of Document Availability	HITSP Notification of Document Availability
HITSP/T31 - Document Reliable Interchange	This Transaction describes a standards-based mechanism to enable the interchange of documents using a reliable messaging system. This allows for a point-to-point communication option for the interchange of documents in the absence of an XDS document sharing infrastructure, or for communication of documents to one or more specific receivers
HITSP/T24 - Pseudonymize	<p>This Transaction is defined to support pseudonymization of protected health information. Pseudonymization: The process of supplying an alternative identifier that permits a patient to be referred to by a key that suppresses his/her actual identification information.</p>
HITSP/TP22 - Patient ID Cross-Referencing	<p>The Patient ID Cross-Referencing (PIX) and Patient Identity Feed Transactions are portions of Interoperability Specifications that deal with identifying and cross-referencing different patient attributes for the same patient</p> <p>The PIX Transaction is intended to provide an (identify patient query / patient(s) identified) response message pair for use wherever such needs exist</p> <p>The Patient Identity Feed Transaction is intended to allow sending of patient identification information from one system to another</p>
HITSP/C25 - Anonymize	The Anonymization Component provides specific instruction for anonymizing data that is ready for transmission to an analytical information resource. This Component is specified only within the context of the data variables associated with a given information resource and data set. Guidance is provided based upon identification risk assessment. Any further use beyond those defined within this construct should undergo a privacy risk assessment and assert mitigating privacy protection measures
HITSP/TP50 - Retrieve Form for Data Capture	Retrieve Form for Data Capture Transaction Package



New Construct	Construct Description
HITSP/T16 - Consistent Time	The HITSP Consistent Time Transaction provides a mechanism to ensure that all the entity systems communicating within the network have synchronized system clocks
HITSP/T17 - Secured Communication Channel	The HITSP Secured Communication Channel Transaction ensures the authenticity, integrity, and confidentiality of transactions, and the mutual trust between communicating parties
HITSP/C26 - Nonrepudiation of Origin	The HITSP Nonrepudiation of Origin Component supports nonrepudiation of origin
HITSP/C19 - Entity Identity Assertion	The HITSP Entity Identity Assertion Component ensures that an entity is the person or application that claims the identity provided
HITSP/T15 - Collect and Communicate Security Audit Trail	The HITSP Collect and Communicate Security Audit Trail Transaction defines and identifies security relevant events and the data to be collected and communicated as determined by policy, regulation, or risk analysis
HITSP/TP30 - Manage Consent Directives	The HITSP Manage Consent Directives Transaction Package describes the messages needed to capture, manage, and communicate rights granted or withheld by a consumer to one or more identified entities in a defined role to access, collect, use, or disclose protected health information (PHI), and also supports the delegation of the patient's right to consent
HITSP/TP20 - Access Control	The HITSP Access Control Transaction Package describes the capabilities needed to manage the security and privacy policies in support of the AHIC and ONC health information exchange Use Cases. Specifically, security policies stipulate the administrative, physical, and technical mechanisms required to enforce jurisdictional and organizational health privacy policies both generally and as they may be expressed in a healthcare consumer's consent directives
Measurement Criteria Document Component	Component supporting communication of document-based structured measures (deferred)
Measurement Criteria Message Component	Component supporting communication of message-based structured measures (deferred)
Case Review Document Component	Document-based Component supporting communication of patient cases for drill-down validation of patient quality data (deferred unless same as Patient Level Quality Data Components)
Case Review Message Component	Message-based Component supporting communication of patient cases for drill-down validation of patient quality data (deferred unless same as Patient Level Quality Data Components)
Quality Measurement Document Component	Component supporting communication of document-based aggregate quality measure reports (deferred)
Quality Measurement Message Component	Component supporting message-based communication of patient level quality data (deferred)
Publish and Subscribe Transaction Package	Transaction Package supporting subscription capabilities to selectively retrieve quality data from a document repository (deferred pending completion of IHE ITI Profile)
Consider cross: domain issue – Cross-TC Transaction Package	Transaction Package supporting IHE XDS affinity domain interoperability for document-sharing functional flows (Cross-TC Effort in progress)
Derived information (including procedure ordered and communications documentation)	Component or Transaction pending further analysis. Effort deferred pending further information analysis and aggregator tooling requirements (deferred)
Validation and data quality checking	Component pending further analysis. The HITSP Population Perspective TC has identified this as a late work item (deferred)



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## 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](http://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
Quality Detailed Use Case, June 18, 2007	AHIC Use Case that is the basis of this Interoperability Specification.
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"> <li>• The scope, reference policy background, and Security and Privacy principles used in the development of the constructs</li> <li>• A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs</li> <li>• A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases</li> <li>• A list of identified gaps and the recommended approaches to resolving those gaps</li> <li>• A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications</li> <li>• A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management</li> <li>• A glossary of terms used in all the Security and Privacy construct documents</li> <li>• 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</li> </ul> <p>HITSP will periodically update this Technical Note as required by the introduction of new contexts for use</p>



## 2.0 INTEROPERABILITY REQUIREMENTS

This section provides a high level description of the Quality Use Case as well as the specific requirements that are extracted from the Use Case. It includes the following information:

- Mapping from the Use Case Requirements to the Derived Interoperability Requirements – this table lists the requirements grouped by actor for each event and related action
- Data Element Requirements – this table further describes the data requirements for each specified interoperability requirement and the business actor that is responsible for the data
- Business Actors – this table defines the business actors that are included for the Interoperability Specification
- High Level Unified Modeling Language (UML) Business Sequence Diagrams – these diagrams are used to describe the interaction between the business actors, and the data involved in each scenario that is documented

### 2.1 USE CASE SYNOPSIS

This section provides a synopsis of the Quality Use Case, including any applicable scenarios that are part of the Use Case.

#### 2.1.1 INTRODUCTION

The Institute of Medicine (IOM) defines Quality as “the degree to which health services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge” (IOM, 1990). The American Health Information Community (AHIC) has identified and prioritized several health information technology (HIT) applications, or “breakthroughs,” that could produce a specific tangible value to healthcare consumers. To address one of these breakthrough areas, the Quality Work Group was formed and given the broad charge to recommend to the AHIC how HIT can: 1) provide the data needed for quality measures; 2) automate the measurement, feedback and reporting of a comprehensive current and future set of quality measures; 3) accelerate the use of clinical decision support to improve performance on these quality measures; and 4) define how performance measures should align with the capabilities and limitations for HIT.

While the Quality Work Group seeks to meet its broad charge, this Use Case focuses on the capabilities and functionality needed to measure and report on hospital and clinician quality and the use of quality measures to support clinical decision making in an interoperable healthcare system. Currently quality measurement is often labor-intensive, and involves the reporting of disparate measures to numerous requesting organizations, resulting in information that is not consistent across reporting entities.

Consumers are still seeking useful, relevant information with which to make informed choices about their healthcare. While there are organizations today that have made significant progress in reaching consensus on what to measure, the maturation of electronic health records (EHRs) and the spread of



EHR adoption creates a unique opportunity to automate, where possible, the measurement, feedback and reporting of healthcare quality.

Consumers could benefit from the measurement, feedback and reporting of 1) hospital-based healthcare quality such as the measures supported by the Hospital Quality Alliance (HQA) and of 2) physician quality, such as the measures supported by the AQA (formerly known as the Ambulatory Quality Alliance), particularly if this information can be integrated into EHR systems within the provider's workflows. Providers may benefit from receiving near-real time feedback regarding quality measurement. Additionally, quality data across multiple providers and entities could be aggregated for the purposes of improving community health, promoting transparency in healthcare, and providing better information regarding the quality and value of healthcare services.

Within the context of the Quality Interoperability Specification, the working assumption is that performance measures have been developed based on evidence-based clinical guidelines. Four areas of concern for long term implementation of the Quality Use Case include coding systems, EHRs, receiving systems and measurement developers. Code systems require some harmonization where there is overlap and additional work where there are gaps in terminologies to manage quality measurement. This Interoperability Specification is intended to take the first step in identifying those issues. Improvement and standardization in coding systems will facilitate evolution of the actors involved in the quality measurement process, EHRs, receiving systems, and measurement developers. As EHR functionality evolves, an increasing number of the data elements will be captured within routine care delivery activities and the guideline elements intrinsic to the measures can be incorporated directly into the care process as clinical decision support. Receiving systems such as third-party payors are also designed to receive administrative, rather than clinical, data. As these receiving systems evolve, they are also expected to enable the analysis of more clinical data elements. Measurement and guideline developers have traditionally focused on clinical care elements required for human cognitive processes. These elements do not necessarily translate directly to the electronic clinical data element capture required for measurement or clinical decision support.

Implementing quality reporting by analyzing each quality measure individually in detail will not scale sufficiently to provide a broadly applicable methodology for interoperability. Therefore, the AHIC Quality Work Group commissioned the National Quality Forum to convene a Health Information Technology Expert Panel (HITEP) to create a common list of data element types and subtypes that will enable implementation of a large number of clinical quality measures. The HITEP created a priority matrix to accomplish this task. In this Interoperability Specification the HITSP Population Perspective Technical Committee recommends standards to enable collection of these prioritized data element types and subtypes, facilitating completion of the identified HQA and AQA measures as well as providing a baseline for additional measure specification. The Population Perspective Technical Committee also recommends that standard terminologies be used by measure developers to indicate required inclusion and exclusion criteria for measures. The National Quality Forum, through HITEP, is the conduit for the HITSP Technical Committee to influence change among the measurement and guideline developers. It is expected that





measure development will more rapidly evolve based on incremental implementation of Use Cases. Increased data availability will enhance the ability to repurpose data for quality measurement.

### 2.1.2 USE CASE DESCRIPTION

In January 2007, AHIC approved a recommendation to develop a Use Case that: 1) captures the integration of data to support quality measurement, feedback and reporting into electronic health records (EHRs); 2) begins to use quality measures to support clinical decision making; and 3) allows for the aggregation of quality information across multiple providers and entities to support public reporting of healthcare quality. The recommendation included the following AHIC prioritized needs:

- Hospital-based quality measures (core set):
  - Automate data capture and reporting of HQA measures through EHRs in support of provider workflows; and
  - Communicate HQA measure data to external entities
- Clinician-level measures (core set):
  - Automate data capture and reporting of AQA measures through EHRs in support of provider workflows; and
  - Communicate AQA quality measure data to external entities for aggregation and reporting
- Feedback to Clinicians (self-assessment):
  - Enable real-time or near-real time feedback to clinicians regarding specific quality indicators relevant for a particular patient. This may occur through event detectors in EHRs that identify significant variances in practice. To be meaningful, such event detectors should be based on evidence-based practice guidelines, and driven by clinical information about the patient. If coupled with an automated collection of adherence, non-adherence and exclusion criteria, delivery of high quality care and quality reporting could be enabled as part of the decision-making process
  - Enable provision of tailored performance information to clinicians on quality measures for specific patient groups
- Public Reporting:
  - Aggregate data across multiple sources (claims data, medication data, laboratory data, etc.) to support quality measurement, promote accountability among providers, and aid consumers in making informed choices; and
  - Communicate quality measurement data quickly and clearly in a manner that makes it useful to a wide variety of decision makers, patients, healthcare providers, payers, health plans, and regulators who are involved with this process



### 2.1.3 USE CASE SCENARIOS

Today, measuring quality of care is accomplished by measuring hospital performance and physician performance through HQA and AQA measures respectively. For the purpose of this Use Case, two scenarios are used to depict the information flows of data needed to measure and report quality of hospitals and clinicians, recognizing that AQA measures may expand beyond physicians over time (e.g., Physician Assistants, Nurse Practitioners).

#### 2.1.3.1 Hospital-based Care

This scenario covers the documentation, collection, transmission and feedback of patient information relevant to the calculation of an established quality measure, when care is provided to a patient within a hospital setting. The events and actions within this scenario relate to the measurement, feedback and reporting of quality information related to hospital performance, and may include care provided in hospital-based outpatient departments, emergency departments and hospital-based clinics.

#### 2.1.3.2 Clinicians

This scenario covers the documentation, collection and transmission of patient information relevant to the calculation of an established quality measure for a clinician, where a specific clinician can be identified as responsible for ensuring adherence to best practices. Examples include measurement of clinician performance in both inpatient and outpatient settings, such as physician offices, emergency departments, and surgical settings.

## 2.2 **USE CASE REQUIREMENTS**

This section describes the Use Case requirements and outlines all the given scenarios at a high level.

The Quality Use Case specifies interactions among actors to inform quality measures, capture and export patient level data for analysis of performance with respect to those measures, and aggregate such data and reporting locally, regionally and centrally to a quality monitoring organization. These actions represent data transport mechanisms that for the most part exist, but are not necessarily coordinated in a robust and clearly defined flow. Therefore, the HITSP Population Perspective Technical Committee will reuse constructs to the extent possible from provider-to-provider and provider-to-patient flows, repurposing them for the Use Case-required analyses and aggregation. Similar to message-based or document-based data transfers, security constructs including pseudonymization and anonymization will also be reused. New constructs will be created only where the Use Case identifies new interoperability requirements.

Widespread adoption of EHRs is a goal of the national Health IT agenda. The AHIC Quality Use Case focuses on: 1) the impact that collection of electronic health information through an EHR has on driving quality of care through better, more comprehensive clinical information at the point of care; 2) measuring and reporting quality with a minimum of burden assessed on the provider; and 3) the aggregation of health information for the purpose of public reporting of quality. This Use Case depicts two scenarios





related to quality measurement, feedback and reporting with respect to a patient's encounter with the healthcare delivery system: quality measurement of hospital-based care and of care provided by clinicians.

This Use Case assumes the presence of EHRs within the healthcare delivery system and promotes the development of longer-term efforts. The Use Case models the exchange of information between the EHR and the quality measurement, feedback and reporting systems. The Use Case allows for a hybrid model of data collection, where claims and or manual data collection will be required to support certain measures that are not supported through EHRs. The Use Case acknowledges the need to include a combination of claims and clinical EHR data. EHR data could be extracted for these patients to provide a richer measure set, with more automation. However, the Use Case acknowledges that manual review and processing will continue to be required in many contexts and settings.

This Use Case does not model systems that may be present in a hospital or clinician practice setting that do not provide input into quality data collection systems nor does it prescribe an approach for the location of data aggregation. The Use Case does describe roles for these processes which may be fulfilled in several different settings. The Use Case also does not describe harmonized quality measures. Separate AHIC processes will determine the initial and subsequent quality measures to be used. The data flows indicated are not intended to be comprehensive or limiting.

There are two scenarios described by the Use Case:

- Hospital-based care -- This scenario covers the documentation, collection, transmission and feedback of patient information relevant to the calculation of an established quality measure, when care is provided to a patient within a hospital setting. The events and actions within this scenario relate to the measurement, feedback and reporting of quality information related to hospital performance, and may include care provided in hospital-based outpatient departments, emergency departments and hospital-based clinics
- Clinicians -- This scenario covers the documentation, collection and transmission of patient information relevant to the calculation of an established quality measure for clinician quality, where a specific clinician can be identified as responsible for ensuring adherence to best practices. Examples include measurement of clinician performance in both inpatient and outpatient settings, including but not limited to physician offices, emergency departments, and surgical settings

The Population Perspective Technical Committee analysis of the events and actions has resulted in limited distinct technical interoperability requirements between these two scenarios.

#### **2.2.1 MAPPING OF USE CASE REQUIREMENTS TO INTEROPERABILITY REQUIREMENTS**

This section contains an extraction of business actors, required interactions and conditions/scenarios from the Use Case into a matrix/table.



**Table 2.2.1-1 Mapping of Use Case Requirements to Interoperability Requirements**

Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s)	Data Requirement Number
<p>6.1 Clinical Information System (or HIS, EHR) (Healthcare Delivery Organizations)</p> <p>7.1 Clinical Information System (or HIS, EHR) (Ancillary Entities, Clinicians)</p>	1 and 2	6.1.1, 7.1.1	6.1.1.1, 7.1.1.1	<p>1) Measure is expressed in a structured, codified format</p> <p>2) Measure may be communicated through point-to-point (XML possibly) or document sharing (CDA possibly)</p> <p>3) The structured measure must have a human readable component</p> <p>4) Data integrity check</p> <p>5) Vocabulary constraints (system, version, number, text) for measure numerator/denominator sections</p> <p>6) Measures specify the specific test methodology timing/prioritization</p> <p>For analysis of the data, the receiving end must be able to handle small sample sizes. The criteria for data where there are small numbers to report must be specified by the measure</p> <p>7) Algorithm (e.g. how to compute the measurement calculation and calculation instructions) should be a structured expression. Algorithm/metric guides the output of data elements</p> <p>8) Patient level data are reported to the aggregator to group the data for the measure NOTE: the aggregator may be part of the EMR or other system operated by the healthcare delivery organization.</p> <p>9) The measure must provide the expected abstraction guidelines for hybrid methodology (may be text)</p> <p>10) There must be a standard for the format of the measure and the format of the report</p> <p>Base elements and algorithms for computation of derived variables (e.g. continuous use) are sent as patient level data to an aggregator/processing entity for computation</p> <p>11) The measure must identify the data elements that would determine exclusions (e.g. diagnosis, allergies, medications, problems, procedures and history data)</p>	<p>1 Measure Metadata</p> <p>2 Numerator Inclusion</p> <p>3 Numerator Exclusion</p> <p>4 Denominator Inclusion</p> <p>5 Denominator Exclusion</p>
	1	6.1.1, 7.1.1	6.1.1.2	<p>1) A feedback loop should be available to enable revision to measures</p> <p>2) Security requirement for data integrity</p> <p>3) Validation testing – new construct: Data Quality Validation - May be a Cross-TC effort; Add validation construct</p> <p>4) Measure must identify the data elements for determining denominator and numerator inclusions.</p> <p>5) Measure Incorporated by:</p> <p style="padding-left: 40px;">Routine reporting configuration</p> <p style="padding-left: 40px;">Configure EMR Query supporting selection by: (See data requirement 7)</p>	<p>6 Validation testing data requirements</p> <p>7 Data Requirement for query parameters</p>



Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s)	Data Requirement Number
	2	6.1.1, 7.1.1	7.1.1.2	1) Same as 6.1.1.2 2) Elements required for collection are within the EHR workflow, but how it is put in the workflow and how they are implemented is determined locally	7 Data Requirement for query parameters
	1 and 2	6.1.2, 7.1.2	6.1.2.1, 7.1.2.1	No Interoperability Requirement	NA
	1 and 2	6.1.3, 7.1.3	6.1.3.1, 7.1.3.1	1) This will require a differential/probable diagnosis representation. This is a GAP under referral to the Foundations Committee. This will impact the measures 2) Comfort measures (patient option to not comply with the recommendation); Palliative care for DNR where advance directives (NOTE: PHR interaction possible). May exclude from measures 3) How to compute exclusions (e.g. contraindications, etc) – must be clearly defined in the measure 4) This determination is identified as part of the patient visit. This is decision support that the TC recommends as out of scope for this year 5) Security/Privacy: Opt-out – ability of patient to opt-out of the measure may vary by state 6) The Collaborative for Performance Measure Integration into EHRs currently has a survey nearing completion to identify how to incorporate measures into EHR. The output of the survey and next steps should be better defined in 2007 to help inform our needs 7) The AHIC Work Group is also addressing clinical decision support methodologies through a special task force. The results of these efforts will help inform our work effort	7 Data Requirement for query parameters
	1 and 2		6.1.3.2, 7.1.3.2	1) Exclusion criteria supporting Configuration of EMR Query supporting selection by: (See data requirement 7)	7 Data Requirement for query parameters
	1 and 2	6.1.4., 7.1.4	6.1.4.1, 7.1.4.1	1) The TC requests examples and data requirements for additional data from the HITEP 2) SEE GAP: Coded claim data (e.g. discharge diagnosis) is not typically available until well after discharge 3) Abstracting for hybrid 4) Coding abstraction 5) Data entry 6) This may be collected at the time of care 7) Data may be gathered through alternate mechanisms at this stage including through additional electronic queries	8 Data requirements for additional data



Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s)	Data Requirement Number
	1	6.1.5	6.1.5.1	1) This may be collected at the time of care 2) Data may be gathered through alternate mechanisms at this stage including through additional electronic queries 3) Security/privacy requirement for accountability and integrity, data stewardship 4) For structured report template – can we include ‘additional information with augmented elements’; how to handle the update of the structured report? If the report is updated, how to validate that the data has not been altered to ‘fix’ the results 5) Report template specification 6) The measure must identify non-EMR data elements required 7) A data elements list from AHIC is required and the relationship between those data elements - Data Dictionary 8) The electronically queried systems should be codified 9) Security/privacy auditing requirement – for query of remote resources 10) Requires the ability to augment the data from the paper chart	8 Data requirements for additional data
	2	6.1.5	6.1.5.1	1) Possible requirements for matching patient payor data from hospital-based scenario Health Information Exchange (HIE) process	NA
	2	7.1.5	7.1.5.1	1) Possible requirements for matching patient payor data from clinician-based scenario HIE process	NA
	1 and 2	6.1.6, 7.1.6	6.1.6.1, 7.1.6.1	1) A specification for the format to communicate patient level data, including data elements required for the risk adjustment 2) A data dictionary for required elements 3) Data integration/data quality – look for disparities in data coming, data edits, data outliers, usually conducted in a staging area; validate and authenticate quality of data sent	NA
	1	6.1.6, 7.1.6	6.1.6.2	1) The hospital may do its own aggregation 2) For external aggregators, the source adds integrity checks 3) A specification for automation of validation 4) Workflow issues 5) Quality edits: record level edits, patient level edits 6) When extracting data from registries – may need to re-validate the cohort pool 7) Re-validate complex adjunct measure or new cohort, remove duplicates	NA
	1 and 2	6.1.7, 7.1.7.1	6.1.7.1, 7.1.7.	1) Quality measures are calculated – mathematical formulas must be specified clearly in the measure	NA



Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s)	Data Requirement Number
				(e.g. how to calculate hand washing or smoking cessation) 2) There will need to be terminology mapping 3) There may be a statistician encoding the rules. Transformation mapping 4) The implementation of the mathematical formula is not specified in the Interoperability Specification, it is left to product innovation	
	1 and 2	6.1.7, 7.1.7	6.1.7.2, 7.1.7.2	NOTE: Automated if possible – Nothing to be specified by the TC – we do not anticipate a construct for this action 1) Scoping: Processes for data quality/cleaning are identified as a low priority as an automated process in the context of the Use Case and is therefore deferred; Assume process specification out of scope	6 Validation testing data requirements
	1 and 2	6.1.8, 7.1.8	6.1.8.1, 7.1.8.1	1) Patient level detail data that is maintained by the EMR must be transmitted rather than interpretations and computations of the patient level data. NOTE: the aggregator may be part of the EMR or other system operated by the healthcare delivery organization 2) Any interpretation shall be accompanied by the detailed data that supported the judgment be communicated. This will prevent a requirement to re-retrieve the underlying data 3) The patient level data are transmitted either via an HIE, if available, or by point-to-point exchange to the Multi-entity Measurement and Reporting entity	6 Validation testing data requirements  10 Patient level quality data
	1 and 2	6.1.9, 7.1.9	6.1.9.1, 7.1.9.1	1) A structured approach for this process is needed if possible 2) Patient listings 3) A structured report 4) Human readable 5) Machine readable 6) Changes can be detected 7) Patient level data may be required, and these may need to be re-computed across entities 8) Number of cases in numerator and denominator, required for weighting and the number of cases in the population that it represents (sampling issue, must specify how the sample was done) 9) Aggregation may happen at local entity, 3 <sup>rd</sup> party, or at destination 10) Changes need to be detectable on both a patient level and aggregate level	10 Patient level quality Data  11 Measure Report
	1 and 2	6.1.10, 7.1.10	6.1.10.1, 7.1.10.1	1) May be some future tools that can be included in a system – the interoperability requirements behind such a tool are questionable. This would be future work	Future
	1 and 2	6.1.11,	6.1.11.1,	1) Within decision support. Not an interoperability	NA



Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s)	Data Requirement Number
		7.1.11.	7.1.11.1	problem 2) May be some future tools that can be included in a system – the interoperability requirements behind such a tool are questionable. This would be future work. IS Component for a computerized alert, for instance, would be less likely to be communicated from a third party system requiring interoperability 3) This is an internal system action 4) Scope is limited to communicating the measure results to the decision support actor 5) The transaction between the quality measurement result and the decision support system is not clearly stated in the Use Case, but will be in the system actor/interaction workflow	
	1 and 2	6.1.12, 7.1.12	6.1.12.1, 7.1.12.1.	NOTE: This is process only and the TC does not anticipate a construct to support this action	NA
6.2, 7.2 Information Exchange (HIE)	1 and 2				NA
	1 and 2	6.2.1, 7.2.1		1) Will leverage our current PIX/PDQ constructs	NA
	1 and 2	6.2.1, 7.2.1	6.2.1.1, 7.2.1.1	1) Conforms to HIPAA 2) Security & Privacy access control - Privacy Policy review is required for linking across payors for re-disclosure; covered entities organize into an OHCA (Organized Healthcare Arrangement) - Consent/authorization for PHR; PHR is out of scope	NA
	1 and 2	6.2.2, 7.2.2.		1) Can leverage prior pseudonymization construct 2) The Anonymize specification will require a new risk analysis (dependent upon dataset). Could be cumbersome for roll-up into different age-groupings for instance	NA
	1 and 2	6.2.2, 7.2.2.	6.2.2.1, 7.2.2.1	1) Functionality is provided to re-link data to a specific patient for authorized entities 2) The pseudonymization specification will require updating or a new construct to be developed for re-identification 3) Consider cross-domain issue	NA
	1 and 2	6.2.2, 7.2.2.	6.2.2.2, 7.2.2.2	1) It is possible to automate; may be procedural process; (e.g., check if xyz populated, then kick out) 2) May be nothing to be specified by the TC – we do not anticipate a construct for this action. Construct may include notifications 3) Processes for checking de-identification and pseudonymization identified as a low priority as an automated process in the context of the Use Case and is therefore deferred	NA
6.3, 7.3 Multi-	1 and 2				NA



Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s)	Data Requirement Number
Hospital Measurement and Reporting					
	1 and 2	6.3.1, 7.3.1	6.3.1.1, 7.3.1.1	1) Should be able to receive via email and other mechanisms 2) May retrieve using XDS Provide/Register Query 3) May communicate with message sender/receiver	10 Patient level quality data
	1 and 2	6.3.2, 7.3.2	6.3.2.1, 7.3.2.1	1) Preview report (content construct) Complex effort Standards HL7 Structured Report as a candidate 2) Volume/complexity may vary	Future
	1 and 2	6.3.3, 7.3.3		1) Can leverage a communication construct for media or email exchange	11 Measure Report
	1 and 2		6.3.3.1, 7.3.3.1	1) Data requirements for patient listing 2) Data requirements for Measure Report	10 Patient level quality data 11 Measure Report
	1 and 2	6.3.4, 7.3.4			
	1 and 2		6.3.4.1, 7.3.4.1	1) Workflow invoking prior constructs and processes. No new construct 2) Information requirements (e.g. version; flag; review XDS update where used for storage) 3) Communication issue to trigger 'recalculate' or is this a manual trigger/human-initiated process (plan, do, check, act) – phase I this is a manual , non-electronic process	10 Patient level quality data  12 Recalculate requirements
	1 and 2	6.3.5, 7.3.5	6.3.5.1, 7.3.5.1	1) Locally defined. The TC does not anticipate a construct for this action If they can come up with test cases for testing then HITSP would require a methodology for expressing import of those test cases and reporting out. If not, the auditing is a pre-post condition 2) Data integrity requirement for Security and Privacy	Security and Privacy
	1 and 2	6.3.6, 7.3.6	6.3.6.1, 7.3.6.1	1) Report format assumed to be the same as Preview report (content construct) - Complex effort 2) Volume/complexity may vary	11 Measure Report

## 2.2.2 DATA AND INFORMATION REQUIREMENTS MATRIX

This section contains an extraction of data and information requirements with a listing of the actual data elements and information that meet the described data requirements.



The Population Perspective Technical Committee has focused its work around an analysis of the Quality Use Case provided by the AHIC. This work has also been informed by the proceedings of the HITEP.

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

**Table 2.2.2-1 Data Element and Information Requirements**

Requirement Number	Description
Data Requirement 1: Expressing the quality measure criteria including the metadata	<p>Quality Measurement data, including<sup>1</sup> (but not limited to):</p> <ul style="list-style-type: none"> <li>• Measure is expressed in a structured, codified format</li> <li>• Measure may be communicated through point-to-point (XML possibly) or document sharing (CDA possibly)</li> <li>• A human readable translation is required</li> <li>• Data integrity check</li> <li>• Vocabulary constraints (system, version, number, text) for measure numerator/denominator sections</li> <li>• Metadata <ul style="list-style-type: none"> <li>○ Measure ID</li> <li>○ Measure name</li> <li>○ Measure description (including definition of terms)</li> <li>○ Instructions on reporting including frequency, timeframes, and applicability</li> <li>○ Topic type</li> <li>○ Measure developer</li> <li>○ Date sent</li> <li>○ Version</li> <li>○ Approved by</li> <li>○ Date of original approval</li> <li>○ Adoption by regulatory bodies and programs used by the regulatory bodies</li> <li>○ Rationale (includes Clinical area)</li> <li>○ Improvement notation (expected outcome includes clinical area)</li> <li>○ Version changes</li> <li>○ Measurement start date</li> <li>○ Measurement end date</li> <li>○ Contact (not in the collaborative import data)</li> <li>○ Date of version (effective date of the version not in the collaborative import data)</li> <li>○ Level of analysis (who should adopt this)</li> </ul> </li> </ul>
Data Requirement 2: Expressing the quality measure criteria including Numerator Inclusion	<p>Numerator Inclusion – what looking for (study criteria; process/outcome/structure)<sup>2</sup></p> <ul style="list-style-type: none"> <li>• Procedures and diagnostic tests <ul style="list-style-type: none"> <li>○ Ordered – Review possible GAP below</li> <li>○ Performed</li> <li>○ Diagnostic test results (e.g., radiology findings, echo)</li> <li>○ Procedure date/time (supports prior trigger event)</li> </ul> </li> </ul>

<sup>1</sup> Subject to further analysis pending final data dictionary definitions

<sup>2</sup> Subject to further analysis pending final data dictionary definitions





Requirement Number	Description
	<ul style="list-style-type: none"> <li>• Lab information (including all data elements and selected standards identified for lab results from HITSP) <ul style="list-style-type: none"> <li>○ Result value (e.g., lipid measurement for diabetes)</li> <li>○ Lab order (e.g., Hemoglobin A1C)</li> </ul> </li> <li>• Symptom information (e.g., assessment, EKG for chest pain, EKG performed for non-traumatic chest pain in ED)</li> <li>• Physical findings and observations <ul style="list-style-type: none"> <li>○ Vital signs</li> <li>○ Physical exam</li> <li>○ Medication allergies (hypersensitivity reactions)</li> <li>○ True or anticipated side effects (must be distinguished from medication allergies)</li> </ul> </li> <li>• Diagnoses <ul style="list-style-type: none"> <li>○ Principal Diagnosis – for retrospective measures</li> <li>○ Admitting/presumptive for concurrent</li> <li>○ Chronic conditions (e.g., use of appropriate medications for asthma)</li> <li>○ Acute conditions (e.g., appropriate treatment for children with URI)</li> <li>○ Problem list (interdisciplinary)</li> </ul> </li> <li>• Family history</li> <li>• Patient past history</li> <li>• Social history</li> <li>• Allergies (in some situations – conceptually combined with problem list)</li> <li>• Medication existence</li> <li>• Medication administered</li> <li>• Medication order <ul style="list-style-type: none"> <li>○ Authorizing provider</li> <li>○ Drug</li> <li>○ Dose</li> <li>○ Strength</li> <li>○ Dispensed amount</li> <li>○ Refills</li> <li>○ Derived attributes (e.g., continuous use of beta blockers over 6 months) (NOTE: Understood to be a lower priority)</li> <li>○ Managed/given by provider</li> <li>○ Route of entry</li> </ul> </li> <li>• Logical expression (was Boolean logic)</li> <li>• Prior trigger event (e.g., antibiotic prophylaxis 1 hr pre-op, percentage of patients hospitalized with AMI who received persistent beta blocker therapy for 6 months after discharge)</li> <li>• Documentation of clinician-to-clinician communications (e.g., communication by ophthalmologist with physician managing ongoing care)</li> </ul>
Data Requirement 3: Expressing the quality measure criteria including: Numerator Exclusion	Numerator Exclusion <sup>3</sup> <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Procedure</li> <li>• Medication existence</li> </ul>

<sup>3</sup> Subject to further analysis pending final data dictionary definitions



Requirement Number	Description
	<ul style="list-style-type: none"> <li>Medication order</li> <li>Route of entry</li> <li>Lab result</li> <li>Lab order</li> <li>Observation</li> <li>Logical expression (was Boolean logic)</li> <li>Procedure outcome</li> </ul> <p>Calculation-based information</p> <ul style="list-style-type: none"> <li>Consideration of small numbers</li> <li>Risk adjustment (this may be a list of data values that will be used to compute the risk; may be a number if assessed locally; this may be an area for more sophistication and standardization for future constructs)</li> <li>Overall Formula</li> </ul>
Data Requirement 4: Expressing the quality measure criteria including Denominator Inclusion	<p>Denominator Inclusion (collaborative identifies this as 'Denominator Calculation')<sup>4</sup></p> <ul style="list-style-type: none"> <li>DOB</li> <li>Medical home</li> <li>Diagnosis</li> <li>Problem</li> <li>Procedure</li> <li>Medication</li> <li>Procedure result</li> <li>Lab result</li> <li>Lab order</li> <li>Selection period</li> <li>Event type</li> <li>Logical expression (was Boolean logic)</li> </ul>
Data Requirement 5: Expressing the quality measure criteria including Denominator Exclusion	<p>Denominator Exclusions (population selection)<sup>5</sup></p> <ul style="list-style-type: none"> <li>Diagnosis</li> <li>Problem</li> <li>Medication existence</li> <li>Medication order</li> <li>Lab result</li> <li>Lab order</li> <li>Observation</li> <li>Exclusion category</li> <li>Logical expression (was Boolean logic)</li> <li>Adverse Reactions (including Allergy)</li> <li>Contraindications (e.g. medical reason or patient reason if allowable)</li> </ul> <p>Algorithm (e.g. how to compute the measurement calculation/calculation instructions)</p> <p>Abstraction guidelines for hybrid methodology (may be text)</p>

<sup>4</sup> Subject to further analysis pending final data dictionary definitions

<sup>5</sup> Subject to further analysis pending final data dictionary definitions



Requirement Number	Description
Data Requirement 6: Validation testing data requirements	<p>To be developed: Cross-TC Effort –</p> <ul style="list-style-type: none"> <li>Field level Data types/codes</li> <li>Record level Gender, procedures, dx</li> </ul> <p>Data quality edits (e.g. Claim Check) and validation<sup>6</sup> ; edit examples:</p> <ul style="list-style-type: none"> <li>Data edits: Gender codes, demographics – age, sex, valid codes, valid ranges</li> <li>Record level edits (adate &lt; ddate)</li> <li>Patient level (demographic comparisons, clinical likelihood)</li> </ul> <p>Diagnosis/proc mismatch (numerator/denominator inconsistencies)</p>
Data Requirement 7: Query parameters	<p>Clinical Information Resource Query support, including (but not limited to):<sup>7</sup></p> <p>Selection by:</p> <ul style="list-style-type: none"> <li>Diagnosis <ul style="list-style-type: none"> <li>Value</li> <li>Time identified</li> </ul> </li> <li>Problem list <ul style="list-style-type: none"> <li>Value</li> <li>Time identified</li> </ul> </li> <li>Lab result data <ul style="list-style-type: none"> <li>Value</li> <li>Timestamp</li> </ul> </li> <li>Demographics <ul style="list-style-type: none"> <li>Age range</li> <li>DOB</li> <li>Gender</li> </ul> </li> <li>Procedures <ul style="list-style-type: none"> <li>Value</li> <li>Timestamp</li> </ul> </li> <li>Orders <ul style="list-style-type: none"> <li>Medications</li> <li>Lab</li> <li>Comfort measures (e.g. palliative care), (advanced directives, longer term)</li> </ul> </li> <li>Allergies</li> <li>Medication <ul style="list-style-type: none"> <li>Time</li> </ul> </li> <li>Service Codes (was there an office visit)</li> <li>Vitals</li> <li>Visit Data <ul style="list-style-type: none"> <li>Disposition (transfer, home, snf, hospice, death, ...)</li> <li>Admit date/time</li> <li>Discharge date/time</li> </ul> </li> <li>Imaging results (e.g. ejection fraction) <ul style="list-style-type: none"> <li>Qualitative</li> <li>Quantitative</li> <li>Time resulted</li> </ul> </li> </ul>

<sup>6</sup> Subject to further analysis pending final data dictionary definitions



Requirement Number	Description
	<ul style="list-style-type: none"> <li>○ Modality</li> </ul>
Data Requirement 8: Additional data	Subject to further analysis pending final data dictionary definitions from HITEP: May be un-necessary
Data Requirement 9: Patient level quality data	<p>Clinical Information transmitted to aggregator (NOTE: the aggregator may be part of the EMR or other system operated by the healthcare delivery organization), including (but not limited to)<sup>8</sup>:</p> <ul style="list-style-type: none"> <li>• Procedures and diagnostic tests <ul style="list-style-type: none"> <li>○ Ordered – Review possible GAP below</li> <li>○ Performed</li> <li>○ Diagnostic test results (e.g., radiology findings, echo)</li> <li>○ Procedure Date/time (supports prior trigger event)</li> </ul> </li> <li>• Lab information (including all data elements and selected standards identified for lab results from HITSP) <ul style="list-style-type: none"> <li>○ Result value (e.g., lipid measurement for diabetes)</li> <li>○ Lab order (e.g., Hemoglobin A1C)</li> </ul> </li> <li>• Symptom information (e.g., assessment, EKG for chest pain, EKG performed for non-traumatic chest pain in ED)</li> <li>• Physical findings and observations <ul style="list-style-type: none"> <li>○ Vital signs</li> <li>○ Physical exam</li> <li>○ Medication allergies (hypersensitivity reactions)</li> <li>○ True or anticipated side effects (must be distinguished from medication allergies)</li> </ul> </li> <li>• Diagnoses <ul style="list-style-type: none"> <li>○ Principal Diagnosis – for retrospective measures</li> <li>○ Admitting/presumptive for concurrent</li> <li>○ Chronic conditions (e.g., use of appropriate medications for asthma)</li> <li>○ Acute conditions (e.g., appropriate treatment for children with URI)</li> <li>○ Problem list (interdisciplinary)</li> </ul> </li> <li>• Family history</li> <li>• Patient past history</li> <li>• Social history</li> <li>• Allergies (in some situations – conceptually combined with problem list)</li> <li>• Prior trigger event (e.g., antibiotic prophylaxis 1 hr pre-op, percentage of patients hospitalized with AMI who received persistent beta blocker therapy for 6 months after discharge) – See procedure date/time, medication administered date/time – derived element – phase II</li> <li>• Documentation of clinician-to-clinician communications (e.g., communication by ophthalmologist with physician managing ongoing care) See Gap Derived Element and phase II plans</li> <li>• Arrival time: measure must define arrival (Arrival is a LOINC context, HL7 Timestamp; may be a data field; source and standard depends) See Assumptions</li> <li>• Comfort Measures</li> <li>• Onset date/time - Not yet an expert panel requirement-Deferred</li> <li>• Discharge disposition (e.g. death, transfer to home/hospice/snf/AMA) – can use standard claims-based codes – look up standard name (HL7 – UB92 field - leverage what was already cited in</li> </ul>

<sup>7</sup> Largely influenced by what is provided by AHIC. Subject to further analysis pending final data dictionary definitions

<sup>8</sup> Subject to further analysis pending final data dictionary definitions



Requirement Number	Description
	<p>encounter constructs)</p> <ul style="list-style-type: none"> <li>Medication administered (is in the surgical cluster) <ul style="list-style-type: none"> <li>Medication Administered date/time</li> </ul> </li> <li>Discharge instructions</li> <li>Demographics <ul style="list-style-type: none"> <li>Age?</li> <li>Year-Month of Birth</li> <li>Gender</li> </ul> </li> <li>Medication Ordered <ul style="list-style-type: none"> <li>Authorizing provider</li> <li>Drug</li> <li>Dose</li> <li>Strength</li> <li>Dispensed amount</li> <li>Refills</li> <li>Derived attributes (e.g. continuous use say of beta blockers over 6 months)</li> </ul> </li> <li>Consult ordered/Consult result with appropriate components (e.g. an eye exam with appropriate components – retinopathy; provides a dx ICD can help, but may not be sufficient) See GAP</li> <li>Visit data (EMR billing codes – CPT E and M codes)</li> <li>DRG can be derived (analyze to verify that we have all of the input variables)</li> </ul>
Data Requirement 11: Measure Report	Measure Report – TBD depends upon AHIC data requirements/measures <sup>9</sup>
Data Requirement 12: Recalculate requirements	Information requirements (e.g. version; flag; Review XDS update where used for storage) <sup>10</sup>

### Quality Data Elements

In fulfillment of data and information requirements #10, the following provisional data dictionary was generated by the HITSP Population Perspective Technical Committee based upon measure requirements provided by the HITEP. Standards selected by the HITSP Population Perspective Technical Committee to constrain the vocabularies used for interoperability are provided. The list of constraints is harmonized with that provided by the existing 2006 HITSP Interoperability Specifications.

**Table 2.2.2.1-1 Data Elements Cross Reference**

DATA ELEMENTS CROSS REFERENCE	
Column	Definition
HITEP Data Element	Data element name/identifier as listed by Health Information Technology Expert Panel of the National Quality Forum (NQF) for the Identification of Core Data Elements and Prioritization of AQA and HQA Performance Measures for Electronic Healthcare Information Systems

<sup>9</sup> Subject to further analysis pending final data dictionary definitions

<sup>10</sup> Subject to further analysis pending final data dictionary definitions



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 2.2.2.1-2 Base Facility Data Elements**

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 2.2.2.1-3 Patient Data Elements**

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)
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 2.5 Table 001 Administrative Sex M Male F Female U Undifferentiated	



PATIENT DATA ELEMENTS					
HITEP(*)/Use Case Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
Visit data	Visit data	Electronic medical records billing codes		CPT Evaluation and Management Codes	
location-source/current/target*	Patient Class	General type of patient, e.g., Inpatient, Outpatient, Emergency	Coded	HL7 2.5.5 Table 0004 Patient Class, ActEncounterCode subset of HL7 V3 ActCode, limited to IMP, AMB, EMER corresponding 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
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	



PATIENT DATA ELEMENTS					
HITEP(*)/Use Case Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
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
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 2.2.2.1-4 Clinical Data Elements**

CLINICAL DATA					
HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
Problem Data					
diagnosis-output (problem list)*; history-behavioral (smoker)*; history-enrollment trial*; history-symptoms*	Problems	Interdisciplinary patient issues, 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 <b>problem</b> 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  NOTE: History-symptoms may be present in an interdisciplinary problem list but likely not present in most cases <sup>14</sup>
problem list*;	Problem Date	This is the range of	Timestamp		





CLINICAL DATA					
HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
history-behavioral (smoker)*; history-enrollment trial*; history-symptoms*		time of which the problem was active for the patient			
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		
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)



CLINICAL DATA					
HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
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	
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	Coded	SNOMED CT Preferred Terms for Severity	



CLINICAL DATA					
HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
		or intolerance			
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 <sup>11</sup>
Diagnosis Type	Diagnosis Type	Type of diagnosis being sent (admitting, working, final)	IS (coded)	HL7 2.5 User-defined Table 0052 - Diagnosis Type	
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	

<sup>11</sup> SNOMED CT has integrated several of the ANA recognized nursing terminologies (Omaha System, CCC, NIC, NANDA, NOC, PND). LOINC, ICNP (International Classification of Nursing Practice), ABC Codes and NMDS (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.



CLINICAL DATA					
HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
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
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 <sup>12</sup>	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 that LOINC, SNOMED CT, and CPT develop and harmonize a suitable coded value set to express order test name and code values NOTE: HL7 Consultation notes out for ballot
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)
Provider Identifier	Provider Identifier	Unique provider (clinician) identifier		NPI	Need clarification from HITEP regarding provider-patient relationship (e.g.

<sup>12</sup> 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					
HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
					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 <sup>13</sup> , 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 <sup>13</sup>	Likely to be text in existing systems, some may be codified in nursing terminologies which can be mapped to SNOMED <sup>13</sup>
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



CLINICAL DATA					
HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
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.
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 HL7TriggerEvent Code	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 meds 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	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



CLINICAL DATA					
HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
		resistance/complications			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 meds written post-op with appropriate frequency, so discontinue order as a data element might not be needed.
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
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  NOTE: Gap – we have selected a user defined table; Refer to HL7 and NCPDP identify a standard coded value set for this concept.



CLINICAL DATA					
HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
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
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





CLINICAL DATA					
HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
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
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" 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 V3 ActStatusNormal Vocabulary	Based upon the type of information that can be conveyed in the implementation, the computation for medication outpatient duration may differ
Medication-outpatient duration	Days Supplied		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  Roadmap – follow and update pending the work of the Foundations Committee effort to harmonize medication information; anticipate update to specification to align with that work
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	Continuous use or other derived variables need to have base elements and algorithm needed to compute so patient level data can be sent			Understood to be a lower priority  GAP – Measures need to define derivation for accurate implementation



CLINICAL DATA					
HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
	months)	to aggregator for computing by the physician. The measure definition needs to clearly identify what data elements are required to calculate 'continuous use'			
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
Report date/time	Report date/time	Laboratory microbiology result date/time	TS (Timestamp)	HL7 Timestamp	
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	Report/Reading Date. This date is updated	TS (Timestamp)	HL7 Timestamp	



CLINICAL DATA					
HITEP Concept	HITEP Data Element	Definition	Data Type	Selected Standards	Comments
	date/time	with report corrections and addenda	p)		
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	
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 <sup>13</sup> Or ICD9-CM	Most likely text (alphanumeric) NOTE: ICD-10 can be mapped (unidirectional)

### 2.2.3 IDENTIFICATION OF BUSINESS ACTORS, AND SCENARIOS

This section describes the business actors that impact interoperability requirements for each scenario. A HITSP business actor should generally be an IT system that is directly engaged, and benefits from the real world information interchange defined within a business Use Case action. A business actor may also be a person or organization, however, only IT systems have associated technical actors (see Section 3.2 for technical actors). The table below identifies the significant Use Case business actors, their descriptions and the Use Case scenarios in which they are used.

**Table 2.2.3-1 Business Actors**

Business Actor	Description	Use Case Scenario
Clinical Information System (or HIS, EHR)	Information system supporting the clinical care and information management for organizations such as hospitals and physician practices that manage the delivery of care. They may also include institutional providers of healthcare such as ambulatory care and public health department immunization clinics providing quality data for measure. These business actors may be associated with the following stakeholders and actors referenced in the Quality Use Case: Healthcare Delivery Organizations, Ancillary Entities, Clinicians, Care Delivery Actor	1 and 2



Business Actor	Description	Use Case Scenario
Information Exchange	An Information Exchange is a multi-stakeholder organization that enables the exchange and use of health information, in a secure manner, for the purpose of promoting the improvement of health quality, safety and efficiency. This business actor may be referenced in related materials as RHIO, or HIE. (Optional)	1 and 2
Quality Measure and Reporting Enterprise	Organizations that develop adopt or endorse clinical quality measures. These organizations may also conduct the measurement processing. This business actor may be associated with the following stakeholders and actors referenced in the Quality Use Case: Multi-Hospital Measurement and Reporting, Joint Commission, CMS, NCQA, Destination Agent/Monitor Agent/Measurement System, payers, HIPs (Optional)	1 and 2
Measurement Consumers	Individuals or organizations that retrieve the published quality measures to inform decisions. This business actor may be associated with the following stakeholders and actors referenced in the Quality Use Case: Consumers, HIM Personnel, Healthcare Payors, Healthcare Purchasers, Health Researchers, Public Health Monitoring System, Quality Organizations, Clinicians, Healthcare Delivery Organizations, and Ancillary Organizations	1 and 2
Processing Entities	Organizations that receive results of quality performance (structural, process and outcome measures) and create reports for comparison among various providers in a region or nationally; implementers can be the same organization as the Performance Measure Adopter, or approved 3 <sup>rd</sup> party organizations. These business actors may be associated with the following stakeholders and actors referenced in the Quality Use Case: clearinghouses, data warehouses, third party vendor support, associations providing services, Quality Measurement and Reporting Enterprise Certified Agencies, payers, HIPs (Optional)	1 and 2
Performance Measurement Rules Information Resource (Quality Organizations)	Organizations that provide an electronic resource of codified structured quality measures and measure metadata	1 and 2

#### 2.2.4 HIGH-LEVEL UML BUSINESS SEQUENCE DIAGRAM

This section contains an explanation of the relationship between the business actors and data interactions between the primary actors and alternative actors for each Use Case scenario. The diagrams that follow illustrate each scenario with a representation of a normal sequence of exchange between the primary actors.



Figure 2.2.4-1 Clinician/Hospital Perspective Business Sequence Diagram

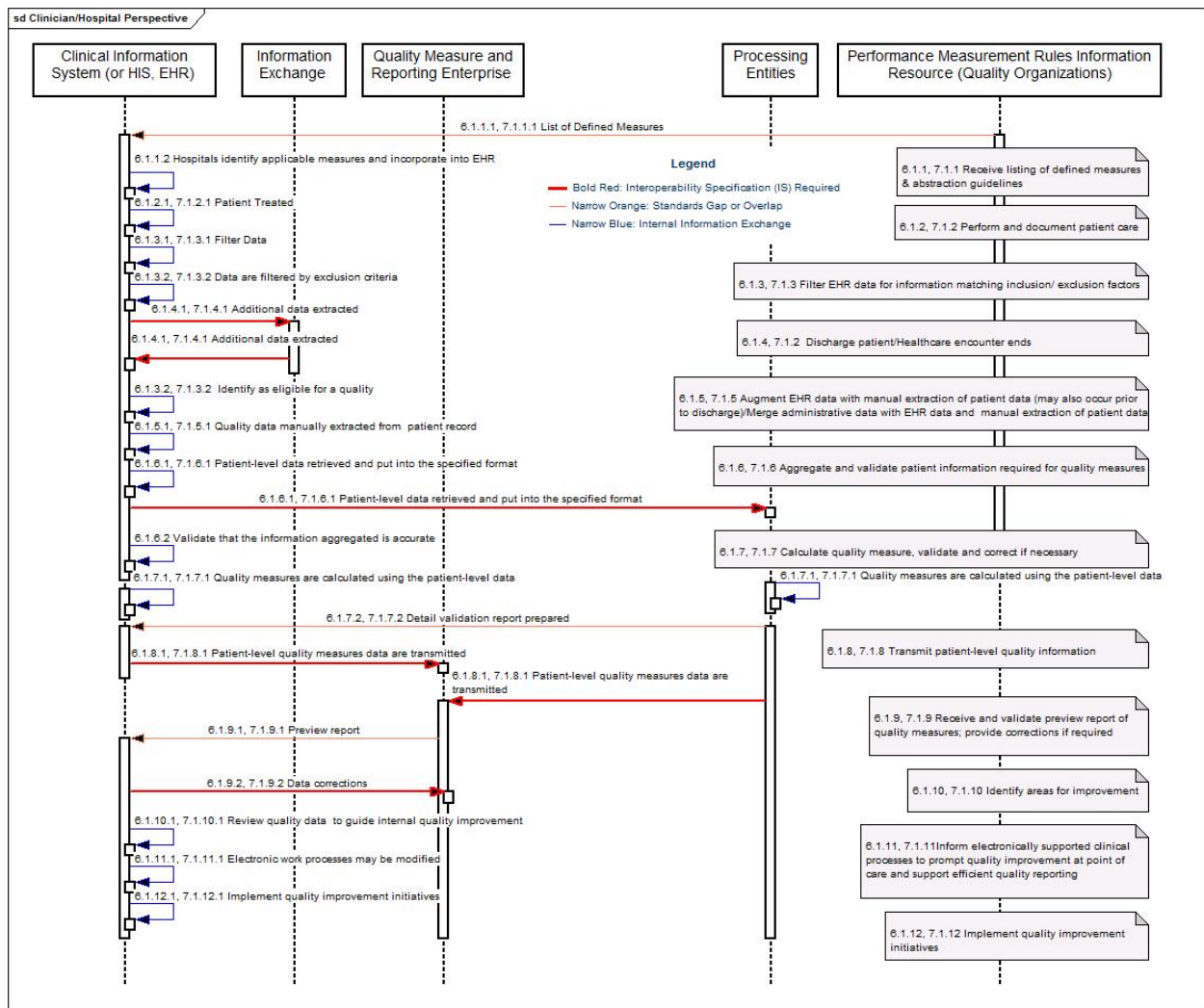
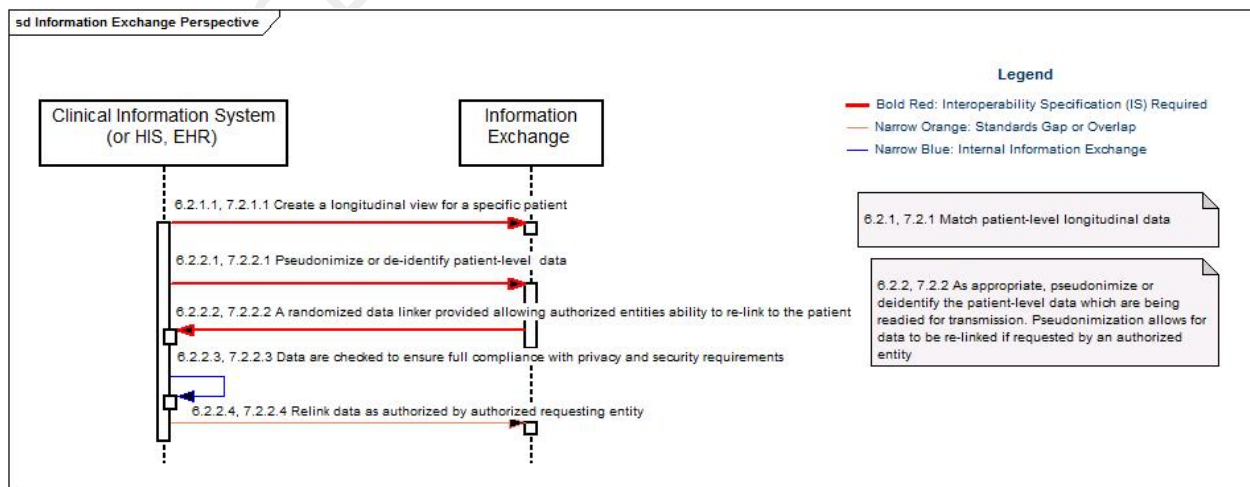
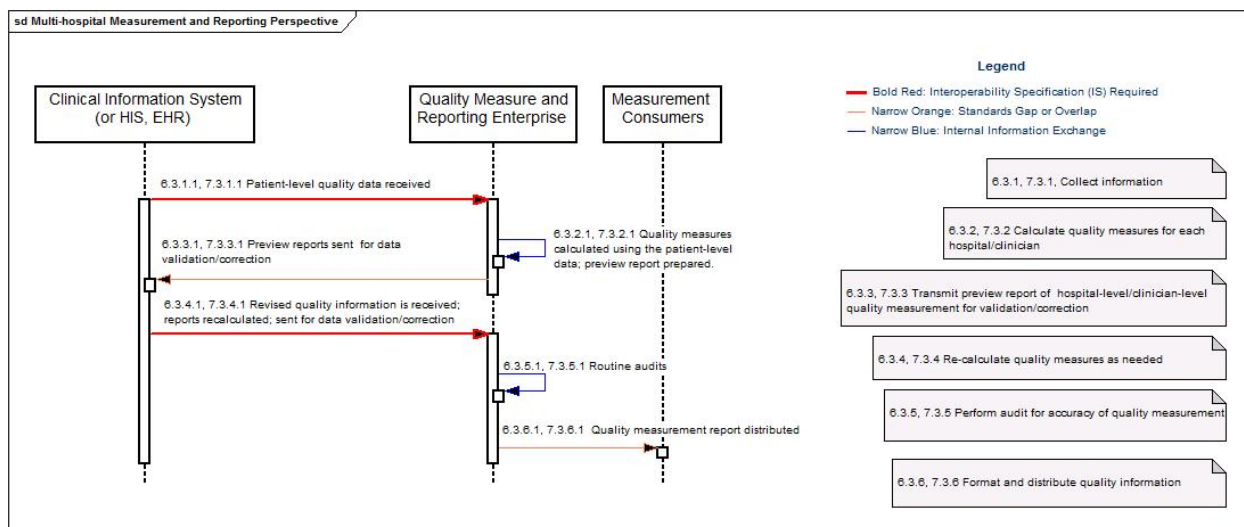


Figure 2.2.4-2 Information Exchange Perspective Business Sequence Diagram



**Figure 2.2.4-3 Multi-hospital Measurement and Reporting Perspective**



### 2.2.4.1 Implementation Variants

There are various environments for capturing quality data. This specification is intended to support multiple implementation architectures. Below, we describe four likely scenarios, all leveraging one or more of the transactions identified in Figure 2.2.4-1. In some environments, information may be analyzed and aggregated locally and in others, the service may be provided by a trusted third party. The first environment is an enterprise where a Clinical Repository is present (Clinical Repository Source). The second environment makes use of a typical interface engine environment where there are distributed applications for ADT, Lab, Rx, Imaging, etc. (Messaging Source). A third possible environment is one where the data sources are from both a clinical repository and messaging (Mixed Source), and a fourth where there is a document sharing infrastructure available for source data and as a destination repository. These scenarios are intended to be illustrative examples. They are not an exhaustive compilation of all environments this Interoperability Specification could support.

#### 2.2.4.1.1 Clinical Repository

In a clinical repository environment all the data needed for Quality can be gathered from the clinical repository (see Figure 2.2.4-1, Clinical Information System Actor B). Database triggers can be used to capture snapshots of data as it is added, updated or deleted from database tables (assuming the repository is built using Report Distribution Management System (RDMS) technology). Other techniques of detecting events may be needed if the repository is using technology other than RDMS, including leveraging HITSP/TP13 V2.1 - Manage Sharing of Documents, HITSP/TP50 - Retrieve Form for Data Capture, or HITSP/TP21 - Query for Existing Data. The actual architecture of the repository will influence what types of events can be used as triggers. For instance, many repositories keep a historical record of all changes to an object being tracked (i.e., a patient, order, result, etc.). In this case, the application may only add information for these objects to the database, adding a new row to tables instead of updating existing rows. Following this case example, it may be difficult to determine specifically what changed. The clinical repository may also supplement information through the use of HITSP/TP21 - Query for Existing





Data, either as part of the information it manages or as part of information that it compiles for transmission to quality analysis or measurement consumers.

In the clinical repository environment it is certainly possible to transmit a snapshot of all the information in the Quality message. It is also possible to send just information regarding data that was changed, typically at a table level. This means if a row in a database table was added/updated/deleted, all the information associated with that row can be transmitted in a transaction. In practice there is a small set of data required for transmission regardless of the specific event.

NOTE: The clinical repository source is well suited for back loading historical information.

This environment can be supported using either the 2.x ORU^R01 or the V3 CDA (with appropriate transport message).

When required by jurisdiction or domain, data may be Pseudonymized and Anonymized prior to transmission to the processing entity for analysis and measurement. Where the clinical information source reporting is also the processing entity, these privacy enhancement steps would likely be omitted.

#### *2.2.4.1.2 Messaging Source*

The messaging source environment basically involves monitoring the message flows between applications in an enterprise and extracting Quality data from appropriate messages (see Figure 2.2.4-1 Clinical Information System Actor B). All of the Quality data elements will not be available in a single view within the messaging source environment. The Quality message component output is a suite of HL7 2.5 messages comprised of source messages that have been normalized to eliminate their variation. Some typical sources of the information include the Census/Registration system, various ancillary systems, and a clinical information system, each of which may be available in different message formats (e.g., due to differing versions of HL7 or other site variations).

It is important to note that the receiver of the Quality data must not only link the data to the appropriate encounter, it must link up data within the encounter appropriately. There may be multiple lab and radiology results associated with an encounter. Each laboratory or radiology result may be transmitted multiple times during an encounter (i.e., preliminary results, final results, corrected results, etc.). These various updates to results must be linked together using appropriate identifiers for the specific results. This processing may be conducted within the Clinical Information System or may be conducted by a Processing Entity.

NOTE: The messaging source environment is not suited for performing a back load of historical encounter information.



#### 2.2.4.1.3 *Mixed Source*

The mixed source environment is likely to be a common environment. In this case some of the Quality data may be available from a clinical repository and some of the Quality data may be available from message flows in the enterprise. It is certainly possible that some Quality information is unavailable from message flows or a clinical repository. In this case, the information may be available in a departmental application (such as an Emergency Department application) and is not electronically transmitted in the enterprise. Given mixed source architecture, each of the information gathering constructs (Traditional HL7 Messaging, HITSP/TP13 V2.1 - Manage Sharing of Documents, HITSP/TP21 - Query for Existing Data, and HITSP/TP50 - Retrieve Form for Data Capture) are available to the implementer to capture appropriate quality data and HITSP/C34 - Patient Level Quality Data Message, and HITSP/C38 - Patient Level Quality Data Document are available to the implementer to communicate the resulting information to the processing entity.

#### 2.2.4.1.4 *Document Sharing*

The Document Sharing environment is likely to be an emerging environment in many health information exchanges. In such an environment, historical clinical details from the provider sending details as well as other health information exchange providers will become increasingly available, and will enable a rich set of source historical data for quality measurement. These historical documents will be available to the Clinical Information System (see Figure 2.2.4-1 Clinical Information System Actor B), as well as information that may be available through locally accessible resources through HITSP/TP21 - Query for Existing Data and HITSP/TP50 - Retrieve Form for Data Capture. From this source information, data can be Anonymized and Pseudonymized as required by local jurisdiction or domain, and made available through the HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS) construct as a shared document again leveraging HITSP/TP13 V2.1 - Manage Sharing of Documents.





## 3.0 DESIGN

The design for the Interoperability Specification is the result of the requirements analysis and iterative standards selection process. This section describes the events and actions of the design from the specified requirements. It also provides a detailed mapping of the specified requirements to the business and technical actors, and data elements. Groupings of specific actions and actors are illustrated to further describe the relevant interactions as existing or new HITSP constructs required for interoperability.

### 3.1 SCOPE OF DESIGN

This section describes the scope of the design as it relates to the requirements for this Use Case that were identified in section 2.2 above. The scope identifies the assumptions that provide the boundaries for the specification and the constraints that limit the use of the specification. In addition, any pre-conditions, post-conditions and triggers that underlie the interactions between the various actors, data and transactions are provided.

The design leverages existing HITSP constructs and communication methodologies. Additional communication methodologies are identified for consideration of enabling media and email-based communications of quality measures, validation reports, and patient level quality data. There is a significant variation in practice and insufficient standards to express measures and results, requiring significant harmonization and analytical effort to establish a consistent approach for the Interoperability Specifications. Therefore, the Use Case requirements have been scoped into releases to align with expected timelines of parallel efforts at standardization and harmonization in HL7, the Collaborative for Performance Measure Integration into EHRs, and the IHE Quality Domain. The focus of the initial design is to enable electronic communication of patient level quality data. This effort will further inform the requirements for the structured representation of the quality measures, and the aggregate report specifications.

The Population Perspective Technical Committee plans a multi-release approach, with each release adding to the value and capabilities of the proposed constructs. The Population Perspective Technical Committee plans to leverage existing HITSP technical specifications and align with current standardization and profiling efforts, to deliver as Release I, patient level export and communication of quality data. This is based on requirements established by the HITEP prioritized quality measures. Release II will focus on generating standard, machine-readable structures for communicating measure criteria and aggregate-level measurements. Release III will add support for knowledge management, visualization, and user presentation tools.

Release I:

- Establish Transaction Packages and Transactions to complete the access to patient level data required for the Use Case, supporting the wide variety of communication options available to existing and emerging real-world instantiation of the business actors



- Establish first Component to enable the most pressing interoperability issue in the quality measurement process – the standardization of patient level quality data, based on the HITEP data element classes and types required for high priority measure analyses. It is expected that additional measures outside the high priority scope should also be manageable based on this planned Component
- Include Security and Privacy constraints for implementation of the Quality Specifications

The following table identifies constructs that the Population Perspective Technical Committee has addressed in Release I, and which will be required to export and collect patient level quality data to be communicated for upstream aggregation.

**Table 3.1-1 Constructs addressed in Release I**

Item	Existing Work?	Known Gaps?
HITSP/TP13 V2.1 - Manage Sharing of Documents	Reference existing HITSP construct developed by Cross-TC efforts (HITSP/TP13 - Manage Sharing of Documents Transaction Package using IHE-ITI XDS Profile)	No
HITSP/T31 - Document Reliable Interchange	New HITSP Construct for point-to-point communication of documents as defined by the IHEITI XDR Profile	No
HITSP/T24 - Pseudonymize	Reference existing HITSP construct developed by Population Perspective Technical Committee (HITSP/T24 - Pseudonymize) for privacy protection of quality data	No
HITSP/TP22 - Patient ID Cross-Referencing	Reference existing HITSP construct developed by Cross-TC efforts (HITSP/TP22 - Patient ID Cross-Referencing using IHE-ITI PIX Profile)	No
HITSP/T23 - Patient Demographics Query	Reference existing HITSP construct developed by Cross-TC efforts (HITSP/T23 - Patient Demographic Query using IHE-ITI PDQ Profile)	No
HITSP/C25 - Anonymize	Need to conduct the risk assessment of the quality data elements and generate an 'Anonymize' specification for quality data. Should be an update to the existing HITSP/C25 - Anonymize as a new section with requirements specific to quality data	Needs risk assessment and document update to address the quality data set
HITSP/TP50 - Retrieve Form for Data Capture	Reference existing HITSP construct developed by Population Perspective Technical Committee (HITSP/TP50 - Retrieve Form for Data Capture using IHE-ITI RFD Profile)	No automated data population specified (left to implementer)
HITSP/C34 - Patient Level Quality Data Message	New HITSP construct specifying message-based payload for communication of patient level quality data to be analyzed and aggregated by the recipient	See GAPS identified by the Quality IS
HITSP/C38 - Patient Level Quality Data Document	New HITSP construct specifying document-based payload for communication of patient level quality data to be analyzed and aggregated by the recipient	See GAPS identified by the Quality IS
HITSP/TP21 - Query for Existing Data	IHE QED profile (released for public comment in June 2007) to retrieve existing electronic data from other resources	Will provide feedback during public comment for any identified gaps
HITSP/T16 - Consistent Time	HITSP Security and Privacy construct	See HITSP/T16
HITSP/T17 - Secured Communication Channel	HITSP Security and Privacy construct	See HITSP/T17



Item	Existing Work?	Known Gaps?
HITSP/C26 - Nonrepudiation of Origin	HITSP Security and Privacy construct	See HITSP/C26
HITSP/C19 - Entity Identity Assertion	HITSP Security and Privacy construct	See HITSP/C19
HITSP/T15 - Collect and Communicate Security Audit Trail	HITSP Security and Privacy construct	See HITSP/T15
HITSP/TP30 - Manage Consent Directives	HITSP Security and Privacy construct	See HITSP/TP30
HITSP/TP20 - Access Control	HITSP Security and Privacy construct	See HITSP/TP20

The information analysis efforts that will be extended by the HITSP Population Perspective Technical Committee volunteers to establish the patient level quality data message and document specifications will inform the second release deliverables. This second release will address the following gaps identified by the HITSP Population Perspective Technical Committee:

- Lack of standardization for the expression of a measurement
  - The HITSP Population Perspective Technical Committee expects to leverage efforts under way by the Collaborative for Performance Measure Integration with EHR Systems to define an XML schema to express a quality measure as well as existing efforts in HL7 to standardize performance measure definition and structure
  - This work will be coupled with the information analysis efforts to inform the HITSP Measurement Criteria Message Component and the HITSP Measurement Criteria Document Component
  - Until measurement structure is defined it is expected that the measures and their specifications are communicated and manually interpreted and implemented as is done today

The following table identifies constructs that the Population Perspective Technical Committee anticipates to specify for Release II, and which will enable interoperable mechanisms for communication of quality measurement criteria:

**Table 3.1-2 Potential Constructs to be Specified in Release II**

Construct	Construct Description	Known Gaps?	Scale of Work?
Measurement Criteria Document Component	Develop a structured document that will enable electronic communication and processing of quality measurement criteria	We expect to be able to leverage HL7 Structured Reports, which is not yet final. We expect to leverage the information analysis of the HITSP Population Perspective TC in developing the Patient Level Quality Data Components to inform the information analysis efforts for this construct development. We expect to leverage efforts under way by the Collaborative for Performance Measure Integration with EHR Systems to establish an XML schema to	Large



Construct	Construct Description	Known Gaps?	Scale of Work?
		express a quality measure	
Measurement Criteria Message Component	Develop a message based specification that will enable electronic communication and processing of quality measurement criteria	We expect to leverage the information analysis of the HITSP Population Perspective TC in developing the Patient Level Quality Data Components to inform the information analysis efforts for this construct development. We expect to leverage efforts under way by the Collaborative for Performance Measure Integration with EHR Systems to establish an XML schema to express a quality measure	Large
Case Review Document Component	Communicate document-based case level data content for provider review; this may be covered by the Patient level Quality Data Component	There is no standard for content or communication of quality case review reports	Medium-Large
Case Review Message Component	Communicate message-based case level data content for provider review; this may be covered by the Patient Level Quality Data Component	There is no standard for content or communication of quality case review reports	Medium-Large
Patient Export of Quality Data Transaction Package	IHE PEQD profile (released for public comment in June for a 12 month cycle) to specify the export and collection of patient level quality data	Will provide feedback during public comment for any identified gaps	Small-Medium

#### Release III:

Release III adds to the Quality Interoperability Specifications support for the knowledge management, visualization, and user presentation tools. This effort is dependent upon standardization of aggregated measure results. The Technical Committee has not yet identified any current standardization efforts in this area and will refer the gap for SDO action. Once the gap is addressed, then the Population Perspective Technical Committee will prepare the following additional constructs:

**Table 3.1-3 Potential Constructs to be Specified in Release III**

Item	Existing Work?	Known Gaps?	Scale of Work?
Quality Measurement Document Component	Communicate document-based aggregate level quality data	Standardization of aggregated measure results	Medium-Large
Quality Measurement Message Component	Communicate message-based aggregate level quality data	Standardization of aggregated measure results	Medium-Large
Data Validation and Quality Checking Component	Similar practices, but no available standards	Standardization of data quality edits	Medium-Large

These efforts will require continued collaboration with the HITEP who will work with measure developers for standardization and greater completeness of measure specification.



### 3.1.1 ASSUMPTIONS

This section provides an overview of the assumptions, including the circumstances, actors, policies and/or technologies that need to be in place for the design to be completed as specified. Assumptions are different from constraints which are specifically used to narrow the definition, or indicate limitations of the specified interactions.

**Table 3.1.1-1 Assumptions**

Assumption	Scenario
Quality measures are provided	1 (Hospital-based Care) and 2 (Clinicians )
6.1.1, 7.1.1 Initial measures should address data elements that do not require historical data or excessively complex-to-gather data. For the future, the timeframe for historical review should be considered for any measure to be sure the data are available	1 and 2
6.1.1.7.1.1 Measures require sufficient specification to enable the electronic upload and processing of queries without the need for local interpretation. Limitation on potentially ambiguous criteria should be part of the measurement endorsement process. As an example measurement exclusions represented by previous diagnoses or procedure(s) should indicate how far back in time the diagnosis or procedures can be present to qualify (e.g., if it ever existed or if it existed within two years prior to the study year, etc.).	1 and 2
6.1.1.2, 7.1.1.2 Hospital determination is outside the electronic data flow	1 and 2
6.1.5, 7.1.5 The early implementation measures will be selected that do not require augmentation. The alternative may require an additional manual step	1 and 2
6.1.2, 7.1.5: The 'EHR' referenced may include any information system contained in any clinical and/or financial system supporting patient care and may be used for quality analysis; Augmentation is information that does not exist in an electronic form in the described systems	1 and 2
6.1.7.10.1, 7.1.10.1 process specification out of scope	1 and 2
Claims data are available to CIS during compilation of historical and supplemental information retrieval	1 and 2
Payor data are available only to the aggregator, and this may be a problem for validator in step 6.1.9. Specification for communication of payor data to the aggregator is deferred	1 and 2
Attribution will be fairly applied by measure receivers	1 and 2
<p>Specification will be scoped for first release:</p> <p>The TC evaluated the data element types and sub-types contained within the HITEP 52 high priority measures</p> <p>Where further understanding was needed, the TC used the following five measures to guide discussion:</p> <p>HQA – Angiotensin Converting Enzyme Inhibitor / Angiotensin Receptor Blocker (ACEI / ARB) order at discharge for patients with AMI and LVSD (also specified in the IHE Quality Domain profile due for public comment this summer)</p> <p>AQA – Antiplatelet therapy for patients with Left Ventricular Systolic Dysfunction (LVSD) (ambulatory – also specified for review by the Collaborative for Performance Measure Integration into EHRs)</p> <p>HQA – Beta Blocker administered within 24 hours of admission for AMI patients</p> <p>AQA - Lipid Management in Patients with Diabetes – ordered annually</p> <p>HQA - CHF Patients with appropriate discharge instruction elements</p> <p>NOTE: The TC strongly believes there is value in aligning with other efforts in the area of quality measurement including the IHE Quality Domain and the Collaborative for Performance</p>	1 and 2



Assumption	Scenario
Measure Integration into EHRs	
If a diagnosis is on the problem list, there is a high likelihood that the patient has the finding, and that this is a level that would trigger the quality measurement	1 and 2
Clinical care documentation is available in an electronic format so that measure data can be provided in electronic form	1 and 2
The data does not come from an EHR in all cases or at this time	1 and 2
6.1.1.2, 7.1.1.2 'These defined quality measures are incorporated into the EHR,' This may be from a surrounding infrastructure around an EHR. Whether or not quality measure rules are incorporated is questionable, but decision support rules and logic representation must be incorporated	1 and 2
Decision support is deferred	1 and 2
6.1.5.1 7.1.5.1: As per HIMSS definition: 'The Electronic Health Record (EHR) is a secure, real-time, point-of-care, patient centric information resource for clinicians. The EHR aids clinicians' decision making by providing access to patient health record information where and when they require it and by incorporating evidence-based decision support. The EHR automates and streamlines the clinician's workflow, closing loops in communication and response that result in delays or gaps in care. The EHR also supports the collection of data for uses other than direct clinical care, such as billing, quality management, outcomes reporting, resource planning, and public health disease surveillance and reporting'	1 and 2
6.1.7.1, 7.1.7.1 Terminology mapping is required Assume that there may be a statistician encoding the rules Transformation mapping Assume that the implementation of the mathematical formula is not specified in the Interoperability Specification and is left to product innovation	
7.1.10.1 Process specification is out of scope	1 and 2
7.1.11.1 This is an internal system action	1 and 2
7.1.11.1 Scope is limited to communicating the measure results to the decision support actor	1 and 2
6.2.2.2, 7.2.2.2 Processes for checking/verifying de-identification as an automated process are identified as a low priority in the context of the Use Case and are therefore deferred; Process specification out of scope	1 and 2
6.3.2, 7.3.2 For each measure, wherever analyzed, the calculation algorithm is the same	1 and 2
Changes in measures can be tracked over time (NOTE: a likely solution is versioning)	1 and 2
The EHR is a resource for structured data	1 and 2
Minimum dataset requirements for quality measurement are established	1 and 2
Codified and structured quality measurement data can be collected from electronic systems accessible to the Clinical Information System (CIS) (NOTE: for the purpose of the Interoperability Specification non-electronic capture systems are out of scope)	1 and 2
Electronic availability of real-time measures are deferred	1 and 2
Decision support based upon quality measurement results is deferred or left to implementer innovation	1 and 2
Interoperability requirements for real-time feedback are out of scope	1 and 2
There will be policy issues surrounding sharing of this data, refuting data pre and post publication, and release of risk-adjusted public dissemination. Internal risk management policies surrounding public disclosures will be defined by organizational and public policy	1 and 2



Assumption	Scenario
Data are patient pseudonymized but provider identified	1 and 2
Security and access protections will assure that data are confidential and protected until approved for publication	1 and 2
There will be a policy for attribution of the patients to the providers	1 and 2
An EHR is in place	1 and 2
Aggregating function within the HIE, but we assume that the aggregator may be inside or outside the organization	1 and 2
Pseudonymization is done within the HIE	1 and 2
Health organization has a system identifying the metrics	1 and 2
The measures and data captured are codified	1 and 2
Where applicable, use existing HITSP constructs and specifications	1 and 2
Whether or not data are manually entered, the transaction must use the standards	1 and 2
The Personal Health Record (PHR) is out of scope	1 and 2
The quality organization stakeholders include the professional organizations (e.g. AAFP, AAP, ACP, AMA, ACC, AANP)	1 and 2
We begin with well-constrained basic measures that are accessible, ideally already collected, codified, etc	1 and 2
Measures are unambiguous, well-defined, tested, and documented	1 and 2
Measures specify the specific test methodology timing/prioritization	1 and 2
The early measures specify the specific test methodology timing/prioritization. Implementation measures will be selected that require no augmentation. The alternative may require an additional manual step	1 and 2
Data augmentation may be accomplished through additional electronic queries	1 and 2
The 'EHR' referenced may include any information system contained in any clinical and/or financial system supporting patient care and may be used for quality analysis; Augmentation is information that does not exist in an electronic form in the described systems	1 and 2
Data may be gathered through alternate mechanisms	1 and 2
Patient level data must be reported to the aggregator to group the data for the measure	1 and 2
Hospital determination to incorporate measures is outside the electronic data flow	1 and 2
Algorithm/metric defined in the codified measure guides output of data elements	1 and 2
Order/date/time useful for measures that ask whether the order was written The procedure date/time is useful for measures that ask if a procedure was done Result date/time useful for measures that ask for the result	1 and 2

### 3.1.2 CONSTRAINTS

This section describes the constraints that limit the context in which the Interoperability Specification 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.





The following security constraints are specified to fulfill the security requirements of the Use Case and to enable conformance to possible additional policy restrictions.

**Table 3.1.2-1 Constraints**

Constraint	Scenario
The policy of the implementation environment MAY require HITSP/C26 - Nonrepudiation of Origin for one or more information sources initiating a HITSP Transaction with a payload of: HITSP Patient level quality data HITSP Aggregate quality data HITSP Structure Quality Measures	1 and 2
The policy of the implementation environment MAY require HITSP/C19 - Entity Identity Assertion	1 and 2
The policy of the implementation environment MAY require HITSP/C25 - Anonymize	1 and 2
The policy of the implementation environment MAY require HITSP/T24 - Pseudonymize All re-identification events for Pseudonymized quality data shall record the re-identification purpose from the list provided in section 5.3.1 of ISO TS25237 Health Informatics: Pseudonymization	1 and 2
The policy of the implementation environment MAY require HITSP/TP13 V2.1 - Manage Sharing of Documents (including Document Integrity) be implemented for document information source initiating a HITSP Transaction with a payload of: HITSP Patient level quality data HITSP Aggregate quality data HITSP Structure Quality Measures In this case, the "XDS.b" Option shall be used and the XCA Option may be used.	1 and 2
The policy of the implementation environment MAY require the HITSP/TP20 - Access Control on the transaction The policy of the implementation environment MAY require the HITSP/TP20 - Access Control as a pre-condition At least one of the above controls SHALL be implemented	1 and 2

No additional constraints are specified.

### 3.1.3 PRE-CONDITIONS

This section describes the necessary conditions that must be in place prior to the start of each scenario. The pre-conditions are used to convey any conditions that must be true at the outset of a scenario. It describes the context that must be established before the scenario is executed. They are not however the triggers that initiate a Use Case. Where one or more pre-conditions are not met, the behavior of the Use Case should be considered uncertain.

**Table 3.1.3-1 Pre-conditions**

Pre-condition	Scenario
Policy issues for sharing data are identified	1 and 2
Policy for risk-adjustment for public reporting is identified	1 and 2
Public Reporting relation to internal risk management is identified	1 and 2





Pre-condition	Scenario
Public Reporting security/access protection is defined	1 and 2
Policy surrounding refuting the data prior to publication of comparative results is identified	1 and 2
Policy for attribution of the patients to the providers is defined	1 and 2
Policy for authorization is defined	1 and 2
Policy for re-linking is defined	1 and 2
Pre-implementation certification/audit of the process (e.g. integrator/vendor certification)	1 and 2
Measures of quality healthcare delivery, whether structural, process or outcome related that are based on evidence and the participants of both edges of the NHIN have agreed to utilize these measures for a number of decision points	1 and 2
This specification will assume clearly defined measures as a pre-condition. (See AQA for Heart Failure set of measures as an example of a clearly defined measure)	1 and 2
Hospitals and clinicians will only receive measures applicable to their population	1 and 2
The formula for a measure should be posted publicly and agreed upon before sent in the encoded measure	1 and 2
A policy is required that indicates that for a measure to be valid it needs all components of the model, and indicates how an organization participates if they can't produce all of the data	1 and 2
HITSP/T16 - Consistent Time SHALL be implemented for each system grouping of actors	1 and 2
HITSP/T17 - Secured Communication Channel SHALL be implemented for each system grouping of actors	1 and 2
HITSP/TP30 - Manage Consent Directives SHALL be implemented for each information source and recipient of HITSP Transactions as a pre-condition with a payload of: HITSP Patient level quality data HITSP Aggregate quality data	1 and 2
HITSP/T15 - Collect and Communicate Audit Trail SHALL be implemented for each system grouping of actors	1 and 2

### 3.1.4 POST-CONDITIONS

This section provides an overview of the conditions or results that must occur at the end of each scenario in order for the scenario to be deemed successfully completed. This includes any required outputs from the scenario, or specific actor states.

**Table 3.1.4-1 Post-conditions**

Post-condition	Scenario
Measures are available for quality improvement feedback and for measurement developer	1 and 2
An audit of queries may be assessed for added efficiency	1 and 2
An audit is performed to ensure the integrity and accuracy of the measurement and reporting program	1 and 2
The information recipient MAY further translate from the standard format to a local format at the system edge	1 and 2



#### 3.1.4.1 Process Triggers

This section describes the triggers, including actors and/or processes, which are necessary to start any scenarios, actions or events. It can be an automatic or manual process or result that in turn starts off another scenario, action or event. A trigger is not the same as a pre-condition that describes a context that needs to be in place at the start of the event.

**Table 3.1.5-1 Process Triggers**

Trigger	Scenario
IHE Patient Encounter Management Profile	1 and 2
New measure or updated measure is ready to be communicated – to publish, record, or send	1 and 2
A pre-defined activity triggers the beginning of analysis (e.g. polling, discharge, end patient encounter, registration for encounter, etc). NOTE this pre-defined activity is an implementation specific criterion	1 and 2
Analysis results in information of interest to the Quality Measure and Reporting Enterprise (e.g. lab result of interest). Specific implementation processes are organization specific	1 and 2
Additional Patient level Quality Data are required for the measure	1 and 2
Additional Historical Patient level Quality Data are required for the measure	1 and 2
Patient level data are ready for submission for measurement calculation	1 and 2
Patient level measurement data requires pseudonymization by policy	1 and 2
Aggregate data are ready for provider review	1 and 2
Validation error identified and patient level data are corrected and update sent for measurement calculation	1 and 2
Provider approves public release	1 and 2

There are several implementation-based triggers for sending patient level Quality data, including the updating of patient-based data at the data source, one indication that 'Patient level data are ready for submission for measurement calculation'. In many instances the updating of data at the data source will generate a local HL7 transaction. These local HL7 transactions will be utilized to create the HL7 V2.5 Quality message transactions. It is understood that these are visit or transaction-based triggers. For population health measurements, there may be additional triggers or methods of determining population for denominators that have yet to be specified. This needs to be defined in a measure to understand how to determine such denominator populations.

#### ***Transactions That Capture the Quality Data Elements***

The tables below list the standard HL7 message triggers that may be supported at the site and that potentially carry the Quality data elements. This list does not account for local variations of HL7 or process workflow differences.



**Table 3.1.5-2 HL7 Messages and Trigger Events for Quality Use Case**

Transaction	Standard Input Type^Trigger
Admit/Visit Notification (ADT/Census System trigger)	ADT^A01
Discharge/End Visit (ADT/Census System trigger)	ADT^A03
Register a Patient (ADT/Census System trigger)	ADT^A04
Change an Outpatient to an Inpatient (ADT/Census System trigger)	ADT^A06
Change an Inpatient to an Outpatient (ADT/Census System trigger)	ADT^A07
Update Patient Information (ADT/Census System trigger)	ADT^A08
Cancel Admit/Visit Notification (ADT/Census System trigger)	ADT^A11
Cancel Discharge/End Visit (ADT/Census System trigger)	ADT^A13
Update Adverse Reaction Information (ADT/Census System trigger)	ADT^A60 (new with later versions of HL7)
Add Patient Account (previous HL7 versions: Add/Update Patient Account) (Financial system trigger)	BAR^P01*
Update Diagnosis/Procedure (Financial system trigger)	BAR^P12*
Post Detailed Financial Transaction (Final Diagnosis)	DFT^P03*
Study Orders (general order messages)	ORM^R01 or newer OMG^O19
Study Findings (result messages)	ORU^R01
Medication Order Messages	OMP^O09
Substance Administration Record	RAS^O17
Patient Problem Message Scenarios – “Add Problem” upon pre-admit or scheduling an admission; “Send Problem/Diagnosis List” triggered upon consult request; adding, correcting, deleting or updating information from point of care, clinical practice management or ancillary systems regarding the creation or update of pathways, problems, diagnoses, or goals are communicated to the clinical repository; a point of care information system triggers a linkage between a problem and a set of ordered interventions initiated by the clinical order entry system	PPR/ACK - Patient Problem Message (Events PC1, PC2, PC3)

## 3.2 DETAILED DESIGN

This section provides a detailed description of the technical design, along with an analysis of the main interactions and decisions between all actors, actions and data in support of the specific requirements for each scenario of the Use Case. In addition, this section provides the data element details and an overview of the HITSP constructs used to meet the business and technical requirements for this Use Case. Any variances in the Security and Privacy implementation are also described here.

Local implementation policy as determined by risk assessment, including assessment of jurisdictional and regulatory requirements, will determine which assurance level of Nonrepudiation of origin is needed. For instance, in document-based transmissions, a low level is offered by the basic use of HITSP/TP13 - Manage Sharing of Documents construct. A medium level of assurance is offered by the use of the HITSP/TP13 construct option called “Document Integrity”. A high level of assurance is offered by the use



of the HITSP/C26 - Nonrepudiation of Origin construct which requires the existence of a Public Key Infrastructure (See HITSP/TN900 for a discussion on the challenges with PKIs).

### 3.2.1 TECHNICAL ACTOR ROLE DESCRIPTIONS

This section contains technical actor role descriptions for all scenarios. Note that a business actor is a representation of a person, IT system, organization or any combination that is engaged, and benefits from the real world information interchange defined by a business Use Case, while a technical actor represents an entity internal to a software application, which is engaged in one or more specific Transactions to support a specific aspect of a real world information interchange (e.g. set of message exchanges). The table below describes the technical actor roles involved and the correlation between active actors.

**Table 3.2.1-1 Technical Actor Role Descriptions**

Technical Actor(s)	Actor Role
Aggregated Measure Consumer for Decision Support	Clinical Decision Support input. To be further specified in later releases of the Quality Interoperability Specification
Analyzer/Aggregator	Information recipient of patient level quality data and information source for aggregate & validation reports using one or more of the above actors. To be further specified in later releases of the Quality Interoperability Specification
Audit Record Repository	This actor provides a repository for audit events. IHE does not specify what analysis and reporting features should be implemented for an audit repository
Audit Record Source	The actor that, on behalf of another actor that performs an action requiring logging, creates and communicates an Audit Record to the Audit Record Repository
Clinical Data Consumer	A clinical data consumer makes use of clinical patient data
Consent Directive Requester	Accesses consent directive located through a Consent Registry from Consent Repositories. Lack of definition in current public comment version
Consent Originator	Captures consent directives and may publish the consent directive as a document. It is responsible for sending Manage Consent Directive Requests to a Consent Repository. It also supplies Metadata to the Consent Repository for subsequent registration of the Consent within a Consent Registry
Consent Registry	Responsible for providing location information and sender notification regarding consent directives. The Consent Registry receives a Manage Consent Directive Metadata Request
Consent Repository	Responsible for both the persistent storage of consent directives as well as for their registration with the appropriate Consent Registry. It assigns a Uniform Resource Identifier (URI) and Metadata such as confidentiality codes to the consent directive for subsequent retrieval by an authorized consumer, e.g., for association with published personal health information or for evaluation at a policy decision point
Content Consumer	Responsible for viewing, import, or other processing of content created by a Content Creator Actor
Content Creator	Responsible for the creation of content and transmission to a Content Consumer
Data Repository (Vital Signs, Problems and Allergies, Diagnostic Data, Medications, Immunizations, Professional Services)	For Quality, these data repositories listed in the next six rows may be accessed to electronically capture source patient level quality data content from remote Clinical Information resources
Diagnostic Data Repository	A Diagnostic Data Repository maintains results from diagnostic tests (e.g., Lab, Imaging, or other test results)



Technical Actor(s)	Actor Role
Document Consumer	The Document Consumer queries a Document Registry for documents meeting certain criteria, and retrieves selected documents from one or more Document Repository actors
Document Recipient	Document message recipient for point-to-point document communication (e.g. for measures, pre-release reports, etc)
Document Registry	The Document Registry maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration
Document Repository	The Document Repository is responsible for both the persistent storage of documents as well as for their registration with the appropriate Document Registry. It assigns a URI to documents for subsequent retrieval by a Document Consumer  The Document Registry maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration
Document Source	The Document Source is the producer and publisher of documents and information. It is responsible for sending documents to a Document Repository. It also supplies metadata to the Document Repository for subsequent registration of the documents with the Document Registry Actor. Also used for point-to-point document exchanges
Form Archiver	The actor responsible for receiving form instance data for archival purposes. For Quality, supports the option to enable manual or cut/paste information capture of patient level quality data content
Form Filler	The actor responsible for retrieving a form from a Form Manager and for submitting form instance data to a Form Receiver. The mechanism by which a unique identification of a form is obtained is outside the scope of the Retrieve Form for Data Capture profile. For Quality, used as an option to enable manual or cut/paste information capture of patient level quality data content. For Quality, option for CIS to enable manual or cut/paste information capture
Form Manager	The actor that supplies a form based upon a request that supplies unique form identification. For Quality, used as an option to enable manual or cut/paste information capture of patient level quality data content
Form Receiver	The actor that receives form instance data. For Quality, supports the option to enable manual or cut/paste information capture of patient level quality data content
Identity Provider	Receives the credentials and identifier from the Entity (principal). It may perform authentication at that point or may require additional authentication from another source (the Service Provider)
Immunizations Data Repository	Maintains patient immunization data
Medications Data Repository	A Medications Data Repository maintains patient medication data
Message Receiver	Supports message-based communications (e.g. for measures, pre-release reports, etc)
Message Sender	Supports message-based information source
Node	The originating or terminating point of information or signal flow in a telecommunications network. This actor is equivalent to the Secure Node in the IHE ATNA Transaction
Notification Receiver	Receives notifications of availability for documents in an XDS registry, and may optionally send acknowledgments of them
Notification Sender	Sends notifications of availability for documents in an XDS registry, and receives acknowledgements of these notifications



Technical Actor(s)	Actor Role
Patient Demographics Consumer	The Patient Demographics Consumer queries the Patient Demographics Supplier to obtain patient demographic data. It may receive matches for one or more patients that enable the selection of the desired patient. For Quality, used for identification of patient historical information for the patient level quality data. For Quality, used for identification of patient historical information for the patient level quality data
Patient Demographics Supplier	The Patient Demographics Supplier receives patient registration and update messages from other systems in the enterprise (e.g., ADT Patient Registration or Health Plan Membership Management systems), which may or may not represent different Patient ID Domains. It responds to queries for information
Patient Identity Source	Sends patient demographic information to the Patient Identifier Cross-Reference Manager. For Quality, used for identification of patient historical information for the patient level quality data
Person Identification Service	Manages identity resolution for persons in support of pseudonymization
PIX Consumer	The Patient Identifier Cross-Reference Consumer either queries for sets of cross-reference patient identifiers. It may also receive notifications about cross-reference changes. For Quality, used for identification of patient historical information for the patient level quality data
PIX Manager	The Patient Identifier Cross-Reference Manager Actor is responsible for creating, maintaining and providing lists of identifiers that are aliases of one another across different Patient Identifier Domains
Portable Media Creator	The Portable Media Creator writes the selected information from a consumer's PHR to media following the directory structure outlined by XDM
Portable Media Importer	The Portable Media Importer processes all the contents written by a Portable Media Creator on the physical media. The Portable Media Importer must successfully process all documents
Problems and Allergies Data Repository	A Problems and Allergies Repository maintains patient problem and allergy data
Professional Services Data Repository	Maintains data about historical or planned visits and procedures
Pseudonymization Service	Supplier of alternative identification information that permits a patient to be referred to by a key that suppresses his/her actual identification information
Service provider	Represents the system providing a service to all entities that need an assertion or authentication. The service (or assertion) provider is the trusted third party issuer of the trustable identity assertion
Service Provider (SP)	The information resource, representing the information repositories and all capabilities that receive, process and fulfill authorized requests. The SP includes any local access decision and enforcement components that are part of the distributed capabilities
Service Provider Access Control Service (SP ACS)	Supports and implements the service-side access control capabilities. This is a service provider actor
Service User	The entity represents any individual entity (such as a clinician or an EHR/PHR system) that needs to make a service request of a Service Provider. The Entity may also be known as a principal and/or entity, which represents an end user, an application, a machine, or any other type of entity that may act as a requester in a transaction. A principal is typically represented in a transaction with a digital identity and the principal may have multiple valid digital identities to use with different transaction
Time Client	Establishes time synchronization with one or more Time Servers using the NTP protocol and either the NTP or SNTP algorithms. Maintains the local computer system clock synchronization with UTC based on synchronization with the Time Servers
Time Server	Provides NTP time services to Time Clients. It is either directly synchronized to a UTC master clock (e.g. satellite time signal) or is synchronized by being grouped with a Time Client to other Time Server(s)
User	The entity that takes on the actor role of initiator or claimant. This is an initiator actor



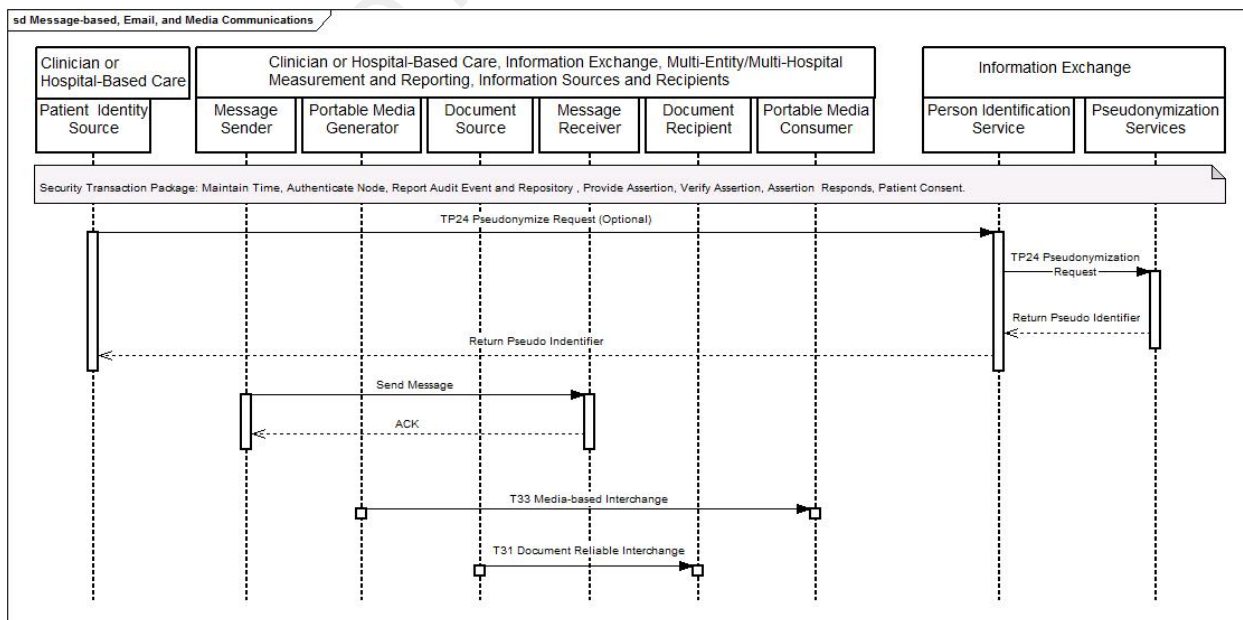
Technical Actor(s)	Actor Role
User Access Control Service (UACS)	The enterprise security service that supports and implements user-side access control capabilities. This is an initiator actor
Vital Signs Data Repository	A Vital Signs Data Repository maintains patient vital signs data

### 3.2.2 SEQUENCE DIAGRAM FOR PROCESS FLOW

This section incorporates the comprehensive business and technical requirements and a detailed analysis of the interactions and decisions undertaken for the primary actions in each Use Case scenario. The UML sequence diagrams used in this section incorporate the detailed data requirements for the selected standards (defined in section 2.2.2) with the technical actors, and their specific and detailed interactions (encapsulated in HITSP constructs). The detailed actor interactions described in these diagrams show all common or independent actors, data, and the actual transactions from the HITSP constructs that are used for the Interoperability Specification.

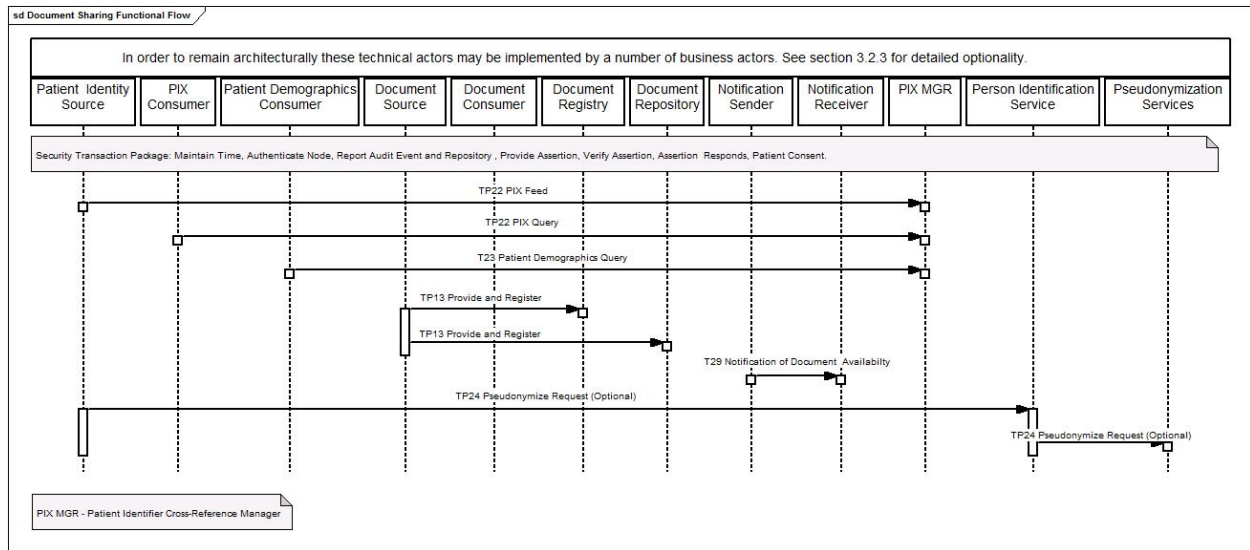
The following diagram includes a number of technical actors, each providing a service to complete the full Use Case for extraction of patient level quality data for analysis, aggregation, internal performance monitoring and submission to destination agencies. The diagram is purposely created to be architecturally neutral. In some settings each technical actor will be represented by a different person, group or electronic system. In many settings, one group or electronic system will serve the roles of many technical actors as depicted in the diagram. There are sufficient potential combinations of actors in different architectures, that examples could add confusion to this document. Therefore, implementation of individual systems should determine which local architecture components represent which technical actors. For simplification, please note that Security and Privacy transactions may not be reflected in the following detailed technical design UML diagram.

**Figure 3.2.2-1 Message-based Communications**

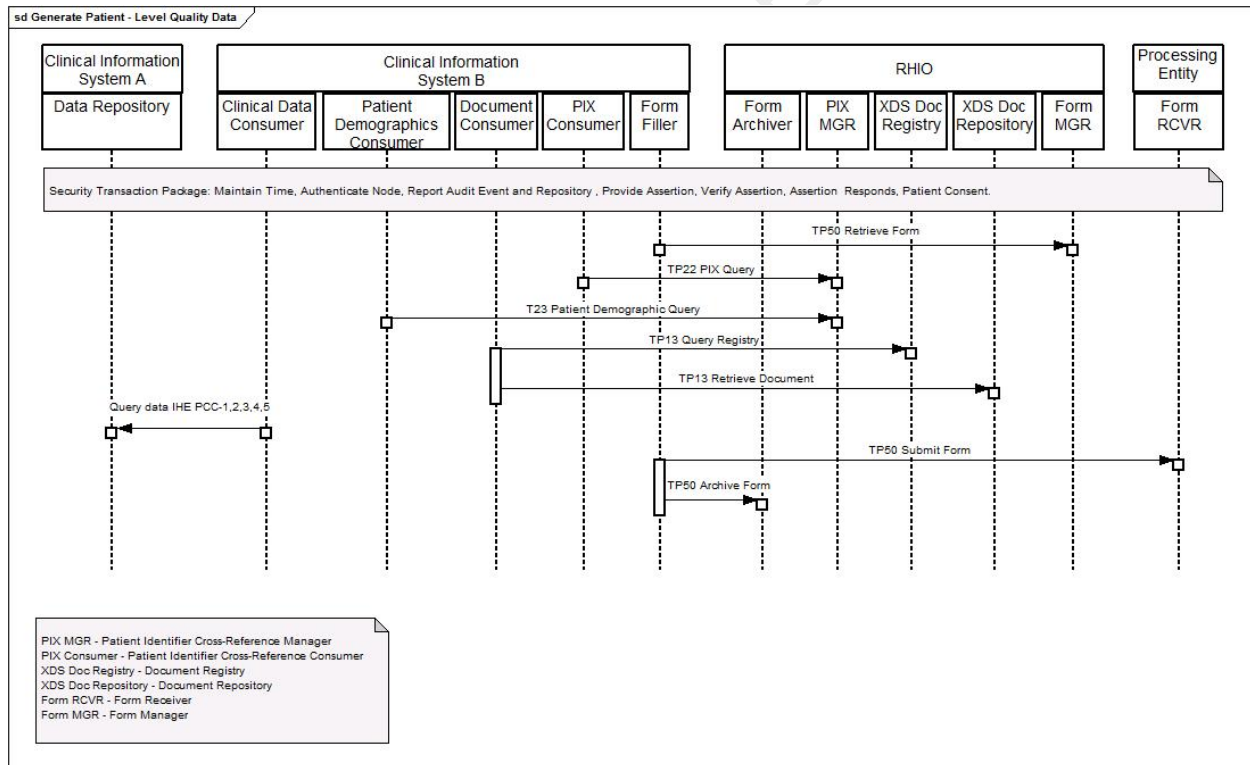




**Figure 3.2.2-2 Document-sharing Communications**



**Figure 3.2.2-3 Preparation of Patient Level Quality Data**





### 3.2.3 MAPPING OF BUSINESS ACTORS TO TECHNICAL ACTORS AND CONSTRUCTS WITH OPTIONALITY

The table below maps the individual business actors defined in the Interoperability Specification and depicted in the above detailed UML sequence diagram. Table 3.2.3-1 below specifies the requirements associated to each business actor in the Interoperability Specification. For each implemented business actor, the table specifies:

1. All Required or Conditionally Required technical actors listed for the business actor shall be supported as specified in the associated construct
2. Optional technical actors listed for the business actor may be supported as specified in the associated construct
3. All Required or Conditionally Required transactions and content subsets listed for each implemented technical actor assigned to the business actor shall be supported as specified in the associated construct
4. Optional transactions and content subsets listed for each implemented technical actor assigned to the business actor may be supported as specified in the associated construct

This table also includes the corresponding technical actors associated with the relevant Security and Privacy constructs that are used for this Interoperability Specification. Section 1.2 provides a summary description of all the referenced HITSP constructs.

The following table includes a number of technical actors, each providing a service to complete the full Use Case for extraction of patient level quality data for analysis, aggregation, internal performance monitoring and submission to destination agencies. The technical/business actor mapping is purposely created to be architecturally neutral. In some settings each technical actor will be represented by a different person, group or electronic system. In many settings, one group or electronic system will serve the roles of many technical actors. There are sufficient potential combinations of actors in different architectures that examples could add confusion to this document. Therefore, implementation of individual systems should determine which local architecture components represent which technical actors.

**Table 3.2.3-1 Business-Technical Actor Mapping to Transaction and/or Content**

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
Clinical Information System (or HIS, EHR) (Healthcare Delivery Organizations, Ancillary Entities, Clinicians) [Care Delivery Actor]	Each of the actors is optional, but at least one must exist. There is a dependency on the source/recipient supporting the exchange				
	Patient Identity Source	C[101]	HITSP/T23	PIX Identity Feed	R
	PIX Consumer	C[101]	HITSP/TP22	PIX Query	R
				PIX Update Notification	O
	Document Source	C[102] C[105]	HITSP/TP13	Provide & Register Document Set-b	C[202]
				Provide & Register Document Set	C[202]
	Document Consumer	C[102] C[106]	HITSP/TP13	Registry Stored Query	C[203]
				Retrieve Document Set	C[203]
				Stored Query	C[203]



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
				Retrieve Document	C[203]
	Patient Demographics Consumer	C[101]	HITSP/T23	Patient Demographics Query	R
	Document Repository	O	HITSP/TP13	Provide and Register Document Set-b	C[204]
				Register Document Set-b	C[204]
				Retrieve Document Set	C[204]
				Register Document Set	C[204]
				Provide & Register Document Set	C[204]
				Retrieve Document	C[204]
	Document Registry	O	HITSP/TP13	Patient Identity Feed	R
				Registry Stored Query	C[205]
				Provide & Register Document Set-b	C[205]
				Stored Query	C[205]
				Provide & Register Document Set	C[205]
	Document Source	C[103] C[105]	HITSP/T31	Provide & Register Document Set.b (online mode)	C[202]
				Provide & Register Document Set (offline mode)	C[202]
	Document Recipient	C[103] C[106]	HITSP/T31	Provide & Register Document Set.b (online mode)	C[202]
				Provide & Register Document Set (offline mode)	C[202]
	Message Sender	C[104] C[105]	HITSP/IS06	Send Message	R
				Receive Ack	R
	Message Receiver	C[104] C[106]	HITSP/IS06	Receive Message	R
				Send Ack	R
	Form Filler	C[109] C[105]	HITSP/TP50	Retrieve form	R
				Submit form	R
				Archive form	O
				Retrieve clarifications	O
	Form Manager (Option for CIS supporting form management locally)	O	HITSP/TP50	Retrieve form	R
				Retrieve clarifications	R
	Form Receiver (Option for CIS supporting form management locally)	O	HITSP/TP50	Submit form	R
	Form Archiver (Option for CIS supporting form management locally)	O	HITSP/TP50	Archive Form	R
	Aggregated Measure Consumer for Decision Support	C[110]	Release II Construct	TBD	NA
	Portable Media Creator	C[105]	HITSP/T33	Distribute Document Set on Media	R
	Portable Media Importer	C[106]	HITSP/T33	Distribute Document Set on Media	R



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Document Recipient	C[113] C[106]	HITSP/T31	Provide & Register Document Set.b (online mode)	C[202]
				Provide & Register Document Set (offline mode)	C[202]
	Clinical Data Consumer	O	HITSP/TP21	Query Vital signs	C[202]
				Query Problems and Allergies	C[202]
				Query Diagnostic Data	C[202]
				Query Medications	C[202]
				Query Immunizations	C[202]
				Query Professional Services	C[202]
	Vital Signs Data Repository	O	HITSP/TP21	Query Vital signs	R
	Problems and Allergies Data Repository	O	HITSP/TP21	Query Problems and Allergies	R
	Diagnostic Data Repository	O	HITSP/TP21	Query Diagnostic Data	R
	Medications Data Repository	O	HITSP/TP21	Query Medications	R
	Immunizations Data Repository	O	HITSP/TP21	Query Immunizations	R
	Professional Services Data Repository	O	HITSP/TP21	Query Professional Services	R
	Notification Receiver	O	HITSP/T29	Receive Notification	R
				Send Acknowledgement	O
	Analyzer/Aggregator	O	Release II Construct	TBD	NA
	Content Creator	R	HITSP/C34	Patient level Quality Message Component	C[201]
		R	HITSP/C38	Patient level Quality Document Component	C[201]
		R	HITSP/TP30	Consent Document Component	R
		C[108]	HITSP/T24	Pseudonymization Request	R
		C[109]	HITSP/C25	Anonymize	R
	Content Consumer	R	HITSP/C34	Patient level Quality Message Component	C[201]
		R	HITSP/C38	Patient level Quality Document Component	C[201]
		R	HITSP/TP30	Consent Document Component	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
Regional Health Information Organizations (RHIO)	Service provider	O	HITSP/C19	Convey Assertion	R
				Verify Assertion	O
	PIX Manager	R	HITSP/TP22	Patient Identity Feed	R
				PIX Query	R
				PIX Update Notification	R
				Pseudonymization Request	R
	Patient Demographics Supplier	R	HITSP/T23	Patient Demographics Query	R
	Document Registry	R	HITSP/TP13	Patient Identity Feed	R
				Registry Stored Query	C[205]
				Provide & Register Document Set-b	C[205]
				Stored Query	C[205]
				Provide & Register Document Set	C[205]
	Document Repository	O	HITSP/TP13	Provide and Register Document Set-b	C[204]
				Register Document Set-b	C[204]
				Retrieve Document Set	C[204]
				Register Document Set	C[204]
				Provide & Register Document Set	C[204]
				Retrieve Document	C[204]
	Person Identification Service	C[108]	HITSP/T24	Person Identity Feed	R
				Person Identity Cross-Reference Query	R
				PIX Update Notification	R
				Pseudonymization Request	R
	Initiating Gateway	O	HITSP/TP13	ITI-38: Cross Gateway Query	R
				ITI-39: Cross Gateway Retrieve	R
	Responding Gateway	O	HITSP/TP13	ITI-38: Cross Gateway Query	R
				ITI-39: Cross Gateway Retrieve	R
	Pseudonymization Service	C[108]	HITSP/T24	Pseudonymization Request	R
	Notification Sender	O	HITSP/T29	Send Notification	R
			HITSP/T29	Receive Acknowledgement	O
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	R	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
Quality Measure and Reporting Enterprise (Multi-Hospital Measurement and Reporting, Joint Commission, CMS, NCQA, etc.)	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	O	HITSP/C19	Convey Assertion	R
				Verify Assertion	O
	Each of the actors are optional, but at least one must exist. There is a dependency on the source/recipient supporting the exchange				
	Document Consumer	C[102] C[106]	HITSP/TP13	Registry Stored Query	C[203]
				Retrieve Document Set	C[203]
				Stored Query	C[203]
				Retrieve Document	C[203]
	Message Receiver	C[104] C[106]	HITSP/IS06	Receive Message	R
				Send Ack	R
	Document Recipient	C[103] C[106]	HITSP/TP31	Provide & Register Document Set.b (online mode)	C[202]
				Provide & Register Document Set (offline mode)	C[202]
	Form Receiver	C[109] C[106]	HITSP/TP50	Submit Form	R
	Portable Media Importer (Media-based information recipient (e.g. for measures, pre-release reports, etc))	C[106]	HITSP/T33	Distribute Document Set on Media	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	R	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	O	HITSP/C19	Convey Assertion	R
				Verify Assertion	O
[Destination Agent/Monitor Agent/Measure ment System] Measurement Consumers (Consumers, HIM Personnel, Healthcare Payors,	Each of the actors are optional, but at least one must exist. There is a dependency on the source/recipient supporting the exchange				
	Document Consumer	C[102] C[106]	HITSP/TP13	Registry Stored Query	C[203]
				Retrieve Document Set	C[203]
				Stored Query	C[203]
				Retrieve Document	C[203]
	Message Receiver	C[104] C[106]	HITSP/IS06	Receive Message	R
				Send Ack	R



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
Healthcare Purchasers, Health Researchers, Public Health Monitoring System, Quality Organizations, Clinicians, Healthcare Delivery Organizations, Ancillary Organizations)	Portable Media Importer	C[106]	HITSP/T33	Distribute Document Set on Media	R
	Document Recipient	C[103] C[106]	HITSP/TP31	Provide & Register Document Set.b (online mode)	C[202]
				Provide & Register Document Set (offline mode)	C[202]
	Notification Receiver	O	HITSP/T29	Receive Notification	R
				Send Acknowledgement	O
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	R	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	O	HITSP/C19	Convey Assertion	R
Verify Assertion				O	
Processing Entities (Clearinghouses, data warehouses, third party vendor support, Associations providing services, Quality Measurement and Reporting Enterprise Certified Agencies)	Each of the actors are optional, but at least one must exist. There is a dependency on the source/recipient supporting the exchange				
	Patient Identity Source	C[101]	HITSP/T23	PIX Identity Feed	R
	PIX Consumer	C[101]	HITSP/TP22	PIX Query	R
				PIX Update Notification	O
	Patient Demographics Consumer	C[101]	HITSP/T23	Patient Demographics Query	R
	Document Source	C[102] C[105]	HITSP/TP13	Provide & Register Document Set-b	C[202]
				Provide & Register Document Set	C[202]
	Document Consumer	C[106]	HITSP/TP13	Registry Stored Query	C[203]
				Retrieve Document Set	C[203]
				Stored Query	C[203]
				Retrieve Document	C[203]
	Message Sender	C[104] C[105]	HITSP/IS06	Send Message	R
				Receive Ack	R
	Message Receiver	C[104] C[106]	HITSP/IS06	Receive Message	R
				Send Ack	R
	Form Filler	C[105] C[109]	HITSP/TP50	Retrieve Form	R
				Submit Form	R
				Archive Form	O
				Retrieve Clarifications	O



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Form Manager	O	HITSP/TP50	Retrieve Form	R
				Retrieve Clarifications	R
	Form Receiver	O	HITSP/TP50	Submit Form	R
	Form Archiver	O	HITSP/TP50	Archive Form	R
	Aggregated Measure Consumer for Decision Support (assuming systems may be manually configured . Option for processing entity providing Clinical Decision Support input)	O	Release III Construct	TBD	NA
	Portable Media Creator	C[105]	HITSP/T33	Distribute Document Set on Media	R
	Portable Media Importer	C[106]	HITSP/T33	Distribute Document Set on Media	R
	Document Source	C[103] C[105]	HITSP/T31	Provide & Register Document Set.b (online mode)	C[202]
				Provide & Register Document Set (offline mode)	C[202]
	Document Recipient	C[103] C[106]	HITSP/T31	Provide & Register Document Set.b (online mode)	C[202]
				Provide & Register Document Set (offline mode)	C[202]
	Clinical Data Consumer	O	HITSP/T21	Query Vital Signs	C[202]
				Query Problems and Allergies	C[202]
				Query Diagnostic Data	C[202]
				Query Medications	C[202]
				Query Immunizations	C[202]
				Query Professional Services	C[202]
	Notification Receiver	O	HITSP/T29	Receive Notification	R
				Send Acknowledgement	O
	Analyzer/ Aggregator	O	Release II Construct	TBD	NA
	Content Creator	O	HITSP/C34	Patient Level Quality Message Component	C[201]
		O	HITSP/C38	Patient Level Quality Document Component	C[201]
		O	HITSP/TP30	Consent Document Component	R
		C[108]	HITSP/T24	Pseudonymization Request	R
		C[109]	HITSP/C25	Anonymize	R
	Content Consumer	O	HITSP/C34	Patient Level Quality Message Component	C[201]
		O	HITSP/C38	Patient Level Quality Document Component	C[201]
		O	HITSP/TP30	Consent Document Component	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	R	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
Performance Measurement Rules Information Source (Quality Organizations providing defined measures – NOTE: These may be the same business actor as the destination agent)	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	O	HITSP/C19	Convey Assertion	R
				Verify Assertion	O
	Each of the actors are optional, but at least one must exist. There is a dependency on the source/recipient supporting the exchange				
	Portable Media Creator	C[105]	HITSP/T33	Distribute Document Set on Media	R
	Message Sender	C[105] C[104]	HITSP/IS06	Send Message	R
				Receive Ack	R
	Document Source	C[105] C[102]	HITSP/TP13	Provide & Register Document Set-b	C[202]
				Provide & Register Document Set	C[202]
	Document Source	C[103] C[105]	HITSP/T31	Provide & Register Document Set.b (online mode)	C[202]
				Provide & Register Document Set (offline mode)	C[202]
	Notification Sender	O	HITSP/T29	Send Notification	R
				Receive Acknowledgement	
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	R	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	O	HITSP/C19	Convey Assertion	R
				Verify Assertion	O

\* **NOTE:** Optionality = “R” for Required, or “O” for Optional, or “C” for Conditional. Conditional footnotes are further described below.

### Actor Optionality Conditions

C[101] - Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer

C[102] - Required for document sharing functional flow.

C[103] - Required for Document Reliable Interchange functional flow.





- C[104] - Required for message-based functional flow.
- C[105] - Business actor shall support at least one of these technical actors to communicate outbound content.
- C[106] - Business actor shall support at least one of these technical actors to receive or retrieve inbound content.
- C[107] - Systems may be manually configured CIS Clinical Decision Support input
- C[108] - Required where pseudonymization is required by the jurisdiction or information sharing agreements.
- C[109] - Required where anonymization is required by the jurisdiction or information sharing agreements.

### Transaction/Content (T/C) Optionality Conditions

- C[201] - Shall support either HITSP Patient level Quality Message Component or Patient level Quality Document Component, or both.
- C[202] - The Actor shall support at least one of these transactions.
- C[203] - The Document Consumer shall support either XDS.a transactions, XDS.b transactions, or both. Where Identity Assertion is required, the Document Consumer shall support XDS.b (Registry Stored Query, Retrieve Document Set)
- C[204] - The Document Repository shall support either XDS.a transactions, XDS.b transactions, or both. Where Identity Assertion is required, the Document Repository shall support XDS.b (Provide & Register Document Set-b, Register Document Set-b, Retrieve Document Set)
- C[205] - The Document Registry shall support either XDS.a transactions, XDS.b transactions, or both. Where Identity Assertion is required, the Document Repository shall support XDS.b to query the registry (Registry Stored Query)

### 3.2.4 CONSTRUCT DEPENDENCIES

The following table shows a list of constructs with their existing dependencies. Dependencies usually exist when there are some additional pre-requisites for a specific construct. To support a dependent construct, a technical actor must implement all the required actions in the pre-requisite construct, or be grouped together with another construct as specified in the table below:

**Table 3.2.4-1 Construct Dependencies**

Construct	Depends On (Name of construct that it depends on)	Dependency Type (Pre-condition, post-condition, general)	Purpose (Reason for this dependency)
HITSP/TP13 - Manage Sharing of Documents	HITSP/C38 - Patient Level Quality Data Document	Pre-requisite	Required for the communication of patient level quality data from hospital and ambulatory EMRs
Message-Based Data Submission	HITSP/C34 - Patient Level Quality Data Message	Pre-requisite	Required for the communication of patient level quality data from hospital and ambulatory EMRs



Construct	Depends On (Name of construct that it depends on)	Dependency Type (Pre-condition, post-condition, general)	Purpose (Reason for this dependency)
Shared Document Resource/Provide and Register (Document Sources)	HITSP/T22 - Patient ID Cross-Referencing Uniquely identify a patient across enterprises	HITSP-DS Actor shall support the HITSP/T22 PIX as part of the HITSP/T24 - Pseudonymize where Pseudonymization is required by the jurisdiction or implementation	Required for consistently assigning the pseudo-identity to a patient across multiple provider locations
Reliable Document Interchange/Provide and Register (Document Source)	HITSP/T22 - Patient ID Cross-Referencing Uniquely identify a Patient across enterprises	HITSP-DS Actor shall support the HITSP/T22 PIX as part of the HITSP/T24 - Pseudonymize where Pseudonymization is required by the jurisdiction or implementation	Required for consistently assigning the pseudo-identity to a patient across multiple provider locations
Message-Based Data Submission	HITSP/T22 - Patient ID Cross-Referencing Uniquely identify a Patient across enterprises	HITSP-DS Actor shall support the HITSP/T22 PIX as part of the HITSP/T24 - Pseudonymize where Pseudonymization is required by the jurisdiction or implementation	Required for consistently assigning the pseudo-identity to a patient across multiple provider locations
Shared Document Resource/Provide and Register (Document Source)	HITSP/T24 - Pseudonymize	Each actor implementing HITSP-DS shall be grouped with the HITSP/T24 - Pseudonymize where Pseudonymization is required by the jurisdiction or implementation	Used to protect confidentiality of patients whose personal health information is sent for quality assessment while assuring that patients can be re-identified
Reliable Document Interchange/Provide and Register (Document Source)	HITSP/T24 - Pseudonymize	Each actor implementing HITSP-DS shall be grouped with the HITSP/T24 - Pseudonymize where Pseudonymization is required by the jurisdiction or implementation	Used to protect confidentiality of patients whose personal health information is sent for quality assessment while assuring that patients can be re-identified
Message-Based Data Submission	HITSP/T24 - Pseudonymize	Each HITSP- Message-Based Data Submission Actor shall be grouped with the HITSP/T24 - Pseudonymize	Used to protect the confidentiality of the patients whose personal health information is sent for quality assessment
HITSP/T24 - Pseudonymize	HITSP/T22 - Patient ID Cross-Referencing Uniquely identify a patient across enterprises	HITSP/T24 Actor shall support the IHE-PIX Integration Profile as part of the HITSP/T24 - Pseudonymize construct	Required for consistently assigning the pseudo-identity to a patient across multiple provider locations

### 3.2.5 ADDITIONAL CONSTRAINTS ON REQUIRED CONSTRUCTS

This section describes the constraints that further limit the constructs that are used by this Interoperability Specification.



**Table 3.2.5-1 Additional Constraints on Required Constructs**

Data Element	Construct	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
Data sent to the shared document repository and recorded in the shared registry must be anonymized unless otherwise permitted through legal and out-of-band arrangements	HITSP/TP13 - Manage Sharing of Documents Resource/provide and register	Information Content	Pre-condition	Required to protect the confidentiality of the patients whose personal health information is sent for quality measurement analysis
Data sent to the shared document repository and recorded in the shared registry must be pseudonymized unless otherwise permitted through legal and out-of-band arrangements	HITSP/TP13 - Manage Sharing of Documents Resource/provide and register	Information Content	Pre-condition	Required to protect the confidentiality of the patients whose personal health information is sent for quality measurement analysis such that the patients can be re-identified as needed to manage significant findings
Patient level data sent to a document recipient and recorded in the shared registry must be anonymized unless otherwise permitted through legal and out-of-band arrangements	HITSP/TP31 - Document Reliable Interchange Resource/provide and register	Information Content	Pre-condition	Required to protect the confidentiality of the patients whose personal health information is sent for quality measurement analysis
Patient level data sent to a document recipient and recorded in the shared registry must be pseudonymized unless otherwise permitted through legal and out-of-band arrangements	HITSP/TP31 - Document Reliable Interchange Resource/provide and register	Information Content	Pre-condition	Required to protect the confidentiality of the patients whose personal health information is sent for quality measurement analysis such that the patients can be re-identified as needed to manage significant findings
	HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	Documents should contain some machine-readable content	Pre-condition	Used to assure machine-consumable information for large volume information exchange and processing
	HITSPTP/13 - Manage Sharing of Documents/ Query Registry Retrieve Document Transaction	Support to return multiple documents for stored Query	General	Asserted to enable quality data retrieval support to enable pull of repository data



	HITSP/TP13 - Manage Sharing of Documents/ Query Registry Manage Sharing of Docs/provide and register	Basic Privacy Patient Consent (BPPC) IHE Integration Profile should be referenced to record the OID of the authorization policy under which the Patient data are disclosed to quality aggregator	Pre-condition	Asserted to record authorized disclosure to in audit logs
Query filters	HITSP/TP21 - Query for Existing Data	Queries shall be expressed using vocabularies identified for each of the data elements indicated in 'standards selected' column of the Quality Data elements (e.g. LOINC, SNOMED CT, and RxNorm)	General	Asserted to assure that systems will support selected standard vocabularies in query and response

In support of Quality, the following XDS Metadata elements are constrained as follows.

**Table 3.2.5-2 Additional Constraints on XDS Metadata Elements**

XDS Metadata Attribute	Optionality	Extended Discussion	Source Type
XDSDocumentEntry.eventCodeList	O	See 0	CADT
XDSDocumentEntry.confidentialityCode	R	See 3.2.5.2	FAD
XDSDocumentEntry.patientID and XDSSubmissionSet.patientID	R	See 3.2.5.3	SAT
XDSDocumentEntry.sourcePatientID and XDSSubmissionSet.sourcePatientID	R	See 3.2.5.4	SAT

#### 3.2.5.1 XDSDOCUMENTENTRY.EVENTCODELIST

The eventCodeList may be populated with quality specific concepts to optimize query capabilities.

#### 3.2.5.2 XDSDOCUMENTENTRY.CONFIDENTIALITYCODE

The confidentialityCode attribute shall contain the following OID when the submitted document has been pseudonymized according to HITSP/24 - Pseudonymize Transaction: **2.16.840.1.113883.3.88.5.2.1**.

#### 3.2.5.3 XDSDOCUMENTENTRY.PATIENTID AND XDSSUBMISSIONSET.PATIENTID

The XDSDocumentEntry.patientID and XDSSubmissionSet.patientID attributes shall contain either the actual patient identifier used by the XDS registry, or shall contain a pseudonymized identifier generated during the HITSP/IST-24 Pseudonymize.



#### 3.2.5.4 XSDDOCUMENTENTRY.SOURCEPATIENTID AND XDSSUBMISSIONSET.SOURCEPATIENTID

The XSDDocumentEntry.sourcePatientID and XDSSubmissionSet.sourcePatientID attributes shall contain either the actual patient identifier used by the document source, or shall contain a pseudonymized identifier generated during the HITSP/24 - Pseudonymize.



## 4.0 STANDARDS SELECTION

This section presents the standards required to support each major Use Case event. Standards selection is based on the following process:

- **Evaluation:** The Technical Committee evaluates the standards using the HITSP Tier 2 Readiness Criteria.
- **Selection:** Based on the Tier 2 evaluations, named standards are selected and listed in the table of selected standards below. 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
- **Gap and Overlap Analysis and Recommendations:** The Technical Committee also identifies and analyzes gaps and overlaps within the standards industry as they related to the specific Use Case. The Technical Committee provides a description of the gaps, including missing or incomplete standards, a description of all overlaps, or competition among standards for the relevant Use Cases, and recommendations for resolving these gaps and overlaps

It is HITSP's policy to incorporate only standards that have been approved according to the formal policy of the standards organization, as defined by HITSP, which publishes the standard. HITSP interprets approval to include Draft Standards for Trial Use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where we believe a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organizations and the HITSP Technical Committee. Thus there are four classes of HITSP-committed standards.

- **Approved for Use** – standards included for unconditional use within a HITSP construct
- **Interim** – standards included for use now within a HITSP construct but for a defined time period or conditional on future actions, e.g., “Intended for Use” standard is available
- **Provisional** - standards that are not yet but are expected to be approved by the standards organization by the time the Interoperability Specification is released by HITSP. A "Provisional" standard becomes an "Approved for Use" standard only if:
  - It is approved by the standards organization by the time that the Interoperability Specification is released by HITSP and
  - It is substantially the same as it was when it was provisionally used and
  - It requires no further action by the Technical Committee
- **Intended for Use** – proposed standards that are road mapped for future use pending actions by the Technical Committee and/or the standards organization. Therefore a standard is defined as “Intended for Use” because it will not be approved by the time that the HITSP construct is released but is sufficiently defined to enable detailed evaluation of how well it will meet technical and interoperability requirements



HITSP may continue to use “Provisional” or “Interim” standards as they existed when incorporated into the HITSP construct if the expected conditions are not satisfied until such time as HITSP can replace it with a more suitable standard. In this circumstance, the Standards Organization would have no responsibility to maintain or correct this artifact. If a standard “Intended for Use” is not developed and approved in terms of time frame or content as expected by the Technical Committee at the time of its initial selection, it may be replaced. All standards used by HITSP must meet the HITSP selection criteria. The use of “Interim” and “Intended for Use” standards will be weighed against the alternative of simply declaring a gap for HITSP and the Standards Organizations to resolve.

## 4.1 TABLE OF SELECTED 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 Interoperability 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 4.1.1)
- 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 4.1.2)

Informative reference standards provide additional background information or guidance, and are not required for interoperability. These standards are not required to implement the Interoperability Specification (see Section 4.1.3)

### 4.1.1 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 Interoperability Specification.

**Table 4.1.1-1 Regulatory Guidance**

Standard	Description
Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification	A listing of national standards plus rules adopted by federal regulation for electronically communicating specified administrative and financial healthcare transactions, and protecting the security and privacy of healthcare information, as applied to the three types of defined covered entities: health plans, healthcare clearinghouses, and healthcare providers who conduct any of the specified healthcare transactions. See the Code of Federal Regulations, Title 45, Parts 160, et. seq. for more information





#### 4.1.2 SELECTED STANDARDS

The following table provides a list of standards that are used to meet information exchange requirements of the Interoperability Specification, and the HITSP constructs that use each standard. A detailed description of each standard is also provided in the appendix.

**Table 4.1-1 Selected Standards Linked to HITSP Constructs**

Standard Name	HITSP Construct	Remarks/ Minor Gaps
American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4); CPT Evaluation and Management Codes	HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	
American Society for Testing and Materials (ASTM) Standard Guide for Electronic Authentication of Health Care Information: # E1762-95(2003)	HITSP/C26 - Nonrepudiation of Origin	
Centers for Medicare and Medicaid Services (CMS) National Provider Identifier (NPI)	HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	
Digital Imaging and Communications in Medicine (DICOM) - Part16: Content Mapping Resource	HITSP/C34 - Patient Level Quality Data Message	
European Telecommunications Standards Institute (ETSI) Technical Specification TS 101 903: XML Advanced Electronic Signatures (XadES)	HITSP/C26 - Nonrepudiation of Origin	
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	HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	
Federal Medication Terminologies	HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	
Health Level Seven (HL7) Version 2.5	HITSP/TP22 - Patient ID Cross-Referencing HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	
Health Level Seven (HL7) Version 2.5/2.5.1	HITSP/T23 - Patient Demographics Query HITSP/C34 - Patient Level Quality Data Message	



Standard Name	HITSP Construct	Remarks/ Minor Gaps
Health Level Seven (HL7) Version 3.0	HITSP/TP21 - Query for Existing Data HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	
Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications RCMR_RM010001 - Data Consent	HITSP/TP30 - Manage Consent Directives	
Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008	HITSP/TP20 - Access Control	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0	HITSP/T24 - Pseudonymize	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a)	HITSP/TP13 - Manage Sharing of Documents HITSP/TP30 - Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b)	HITSP/TP13 - Manage Sharing of Documents HITSP/TP30 - Manage Consent Directives	IHE XDS.b
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement [ITI-18]	HITSP/TP13 - Manage Sharing of Documents HITSP/TP30 - Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement	HITSP/TP13 - Manage Sharing of Documents HITSP/TP30 - Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Patient Demographics Query (PDQ) Integration Profile	HITSP/T23 - Patient Demographics Query	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement - ITI-25 Notification of Document Availability (NAV) Jun 28, 2005	HITSP/T29 - Notification of Document Availability	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) – Trial Implementation	HITSP/TP30 - Manage Consent Directives	



Standard Name	HITSP Construct	Remarks/ Minor Gaps
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 2006-2007 Trial Implementation Supplement Cross-enterprise Document Reliable Interchange (XDR)	HITSP/T31- Document Reliable Interchange	IHE XDR NOTE: offline mode transaction expected to be updated once standards are available for Web Services Offline.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Patient Identifier Cross-Referencing Integration Profile (PIX)	HITSP/TP22 - Patient ID Cross-Referencing	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Audit Trail and Node Authentication (ATNA) Integration Profile	HITSP/T15 - Collect and Communicate Security Audit Trails HITSP/T17 - Secured Communication Channel	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Consistent Time (CT) Integration Profile	HITSP/T16 - Consistent Time	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise User Assertion (XUA)	HITSP/C19 - Entity Identity Assertion	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement Volume 3 – Document Digital Signature (DSG) Content Profile	HITSP/C26 - Nonrepudiation of Origin	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) 2007 – 2008 Supplement, Retrieve Form for Data Capture (RFD)	HITSP/TP50 - Retrieve Form for Data Capture	
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Volume 1, Revision 3.0 2007 - 2008	HITSP/TP21 - Query for Existing Data	
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 3.0, 2007 - 2008, Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile	HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	
International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS)	HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	



Standard Name	HITSP Construct	Remarks/ Minor Gaps
International Classification of Diseases, 9th Revision, Clinical Modifications (ICD-9-CM)	HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) <sup>13</sup>	HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	
International Organization for Standardization (ISO) Health informatics -- Pseudonymisation, Unpublished Technical Specification # 25237	HITSP/C25 - Anonymize	
International Organization for Standardization (ISO) Health Informatics -- Pseudonymization, Unpublished Technical Specification # 25237	HITSP/T24 - Pseudonymize	
Internet Engineering Task Force (IETF) Network Time Protocol (Version 3) Specification, Implementation and Analysis, "Request for Comment" (RFC) # 1305, March, 1992	HITSP/T16 - Consistent Time	
Internet Engineering Task Force (IETF) Simple Network Time Protocol (SNTP) Version 4, "Request for Comment" (RFC) # 2030, October, 1996	HITSP/T16 - Consistent Time	
Logical Observation Identifiers Names and Codes (LOINC®)	HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	
National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm	HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	

<sup>13</sup> 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 Name	HITSP Construct	Remarks/ Minor Gaps
National Uniform Billing Committee (NUBC) Uniform Bill Version 2007 (UB-04) Current UB Data Specification Manual Field 22, Patient Discharge Status, Codes	HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.1, 1.2	HITSP/TP21 - Query for Existing Data	
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) v2.0 OASIS Standard; ITU-T X.1141	HITSP/TP20 - Access Control	
Organization for the Advancement of Structured Information Standards (OASIS) WS-Federation Web Services Federation Language (WS- Federation), Version 1.1, December 2006	HITSP/TP20 - Access Control	
Organization for the Advancement of Structured Information Standards (OASIS) WS-Trust Version 1.3, March 2007	HITSP/TP20 - Access Control	
Organization for the Advancement of Structured Information Standards (OASIS) eXtensible Access Control Markup Language (XACML), ITU-T Recommendation X.1142, February 2005	HITSP/TP20 - Access Control	
Unified Code for Units of Measure (UCUM)	HITSP/C34 - Patient Level Quality Data Message HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	

#### 4.1.3 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 Interoperability Specification.

**Table 4.1.3-1 Informative Reference Standards**

Standard Name	Description/Reason for Use
American National Standards Institute (ANSI) International Committee for Information Technology Standards (INCITS), #359-2004	This standard describes RBAC features that have achieved acceptance in the commercial marketplace. It includes a reference model and functional specifications for the RBAC features defined in the reference model. It is intended for (1) software engineers and product development managers who design products incorporating access control features; and (2) managers and procurement officials who seek to acquire computer security products with features that provide access control capabilities in accordance with commonly known and understood terminology and functional. For more information visit <a href="http://www.ansi.org">http://www.ansi.org</a>



Standard Name	Description/Reason for Use
American Society for Testing and Materials (ASTM) Standard Guide for Privilege Management Infrastructure (PMI) Guidelines: #E2595-07	<p>Defines interoperable mechanisms to manage privileges in a distributed environment. This standard is oriented towards support of a distributed or service-oriented architecture (SOA) where security services are themselves distributed and applications are consumers of distributed services. This standard incorporates privilege management mechanisms alluded to in a number of existing standards (e.g., E1986, E2084). The privilege mechanisms in this standard support policy-based access control (including role, entity and contextual-based access control) including the application of policy constraints, patient requested restrictions and delegation. Finally, the standard supports hierarchical, enterprise-wide privilege management</p> <p>The mechanisms defined in this standard may be used to support a privilege management infrastructure (PMI) using existing public key infrastructure (PKI) technology. This standard does not specifically support mechanisms based on secret-key cryptography. Mechanisms involving privilege credentials are specified in International Organization for Standardization (ISO) 9594-8:2000 (attribute certificates), and Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) (attribute assertions); however, this standard does not mandate or assume the use of such standards</p> <p>Many current systems require only local privilege management functionality (on a single computer system). Such systems frequently use proprietary mechanisms. This standard does not address this type of functionality; rather, it addresses an environment where privileges and capabilities (authorizations) must be managed between computer systems across the enterprise, and with business partners. For more information visit <a href="http://www.astm.org">www.astm.org</a></p>
American Society for Testing and Materials (ASTM) Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems: # E2147-01	<p>E2147-01 "is for the development and implementation of security audit/disclosure logs for health information. It specifies how to design an access audit log to record all access to patient identifiable information maintained in computer systems and includes principles for developing policies, procedures, and functions of health information logs to document all disclosure of health information to external users for use in manual and computer systems. The process of information disclosure and auditing should conform, where relevant, with the Privacy Act of 1974 (1)." For more information visit <a href="http://www.astm.org">www.astm.org</a></p>
Department of Veterans Affairs (VA) National Drug File Reference Terminology (NDF-RT)	<p>It is a description logic-based resource created to support clinical operations at one of the largest healthcare providers in the US, and is part of the Federal Medication Terminologies. The NDF-RT codes can be found on the NCI web site at: <a href="http://www.cancer.gov">www.cancer.gov</a></p>
Digital Imaging and Communications in Medicine (DICOM) Attribute Level Confidentiality Supplement: # 55	<p>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. For more information visit <a href="http://medical.nema.org">http://medical.nema.org</a></p>



Standard Name	Description/Reason for Use
Health Level Seven (HL7) Consent related vocabulary including Confidentiality Codes	HL7 concept domains, including ConfidentialityCodes, ActInformationCategoryCode, ActInformationAccessType, ActInformationAccessContextCode, AuthorizedParticipationFunctionCode, ActPolicyType, ActConsentType, and ActMaskableCode For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008	The Healthcare Permission Catalog provides the necessary content for creating interoperable roles facilitating inter-organizational communications and information sharing among healthcare organizations and their business partners. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) Version 2.5	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 <a href="http://www.hl7.org">www.hl7.org</a> for more information
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0	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. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Volume 2 Transactions, Appendix M Using Patient Demographics Query in a Multi-Domain Environment	Appendix M - Using Patient Data Query (PDQ) in a Multi-Domain Environment, provides an architectural discussion of how Query Parameter Definition, QPD-8 is processed
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Audit Trail and Node Authentication (ATNA) Integration Profile	Audit Trail and Node Authentication (ATNA) establishes the characteristics of a Basic Secure Node. It describes the security environment (user identification, authentication, authorization, access control, etc.) assumed for the node so that security reviewers may decide whether this matches their environments. It defines basic auditing requirements for the node. It defines basic security requirements for the communications of the node using TLS or equivalent functionality. It establishes the characteristics of the communication of audit messages between the Basic Secure Nodes and Audit Repository nodes that collect audit information. This integration profile has been designed so that specific domain frameworks may extend it through an option defined in the domain specific technical framework. Extensions are used to define additional audit event reporting requirements, especially actor specific requirements. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>





Standard Name	Description/Reason for Use
International Organization for Standardization (ISO) Health informatics -- Information technology -- Open Systems Interconnection -- Systems Management: Security alarm reporting function, Technical Specification #10164-- Part 7: Security Alarm Reporting Function, 1992	Establishes user requirements for the service definition needed to support the security alarm reporting function, defines the service provided by the security alarm reporting function, specifies the protocol that is necessary in order to provide the service, defines the relationship between the service and management notifications, defines relationships with other systems management functions, specifies conformance requirements. The security alarm reporting function is a systems management function which may be used by an application process in a centralized or decentralized management environment to exchange information for the purpose of systems management. For more information visit <a href="http://www.iso.org">www.iso.org</a>
International Organization for Standardization (ISO) Health informatics -- Information technology -- Text and office systems - Office Document Architecture (ODA) and interchange format, Technical Report on ISO 8613 implementation testing, Technical Specification # ISO/IEC CD 10183 -- Part 3: Testing procedure.	Specifies a general framework for the provision of access control. The purpose of access control is to counter the threat of unauthorized operations involving a computer or communication system. For more information visit <a href="http://www.iso.org">www.iso.org</a>
International Organization for Standardization (ISO) Health informatics -- Privilege management and access control(PMAC), Technical Specification #22600 -- Part 1: Overview and policy management, July 2006	Supports the needs of healthcare information sharing across unaffiliated providers of healthcare, healthcare organizations, health insurance companies, their patients, staff members and trading partners. It is also intended to support inquiries from both individuals and application systems. For more information visit <a href="http://www.iso.org">www.iso.org</a>
International Organization for Standardization (ISO) Health informatics -- Functional and Structural Roles (ISO SF Roles), Technical Specification #21298 , Draft May, 2007	<p>This document contains a specification for encoding information related to roles for health professionals and consumers. At least four areas have been identified where a model for encoding role information is needed.</p> <p>Privilege management and access control: role-based access control is not possible without an effective means of recording role information for healthcare actors.</p> <p>Directory services: structural roles are usefully recorded within directories of health care providers (see for example, ISO TS 21091 Health Informatics -- Directory services for security, communications, and identification of professionals and patients).</p> <p>Audit trails: functional roles are usefully recorded within audit trails for health information applications.</p> <p>Public key infrastructure (PKI): The three part ISO standard 17090 Health Informatics -- Public Key Infrastructure (PKI) allows for the encoding of healthcare roles in certificate extensions, but no structured vocabulary for such roles is specified. This technical specification identifies such a coded vocabulary.</p> <p>For more information visit <a href="http://www.iso.org">www.iso.org</a></p>
Internet Engineering Task Force (IETF), HTTP HyperText Transfer Protocol HTTP/1.1 (RFC 2616)	The Hypertext Transfer Protocol (HTTP) is an application-level protocol for distributed, collaborative, hypermedia information systems. It is a generic, stateless, protocol, which can be used for many tasks beyond its use for hypertext, such as name servers and distributed object management systems, through extension of its request methods, error codes and headers [47]. A feature of HTTP is the typing and negotiation of data representation, allowing systems to be built independently of the data being transferred. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>



Standard Name	Description/Reason for Use
Internet Engineering Task Force (IETF), MIME Multipurpose Internet Message Extensions (RFC 2045 to RFC 2049)	The first and second documents in this set define MIME header fields and the initial set of MIME media types. The third document describes extensions to RFC 822 formats to allow for character sets other than US-ASCII. The fourth document describes what portions of MIME must be supported by a conformant MIME implementation. It also describes various pitfalls of contemporary messaging systems as well as the canonical encoding model MIME is based on. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>
Internet Engineering Task Force (IETF), SMTP Simple Mail Transfer Protocol (RFC 2821)	The objective of the Simple Mail Transfer Protocol (SMTP) is to transfer mail reliably and efficiently. SMTP is independent of the particular transmission subsystem and requires only a reliable ordered data stream channel. While this document specifically discusses transport over TCP, other transports are possible. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>
Internet Engineering Task Force (IETF), The MIME Multipart/Related Content-type (RFC 2387)	The Multipart/Related content-type provides a common mechanism for representing objects that are aggregates of related MIME body parts. This document defines the Multipart/Related content-type and provides examples of its use. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) Core v2.0 OASIS Standard; ITU-T X.1141	SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) Web Services Security SOAP Message Security Version 1.0	Describes enhancements to SOAP messaging to provide message integrity and confidentiality. The specified mechanisms can be used to accommodate a wide variety of security models and encryption technologies. This specification also provides a general-purpose mechanism for associating security tokens with message content. No specific type of security token is required, the specification is designed to be extensible (i.e., support multiple security token formats. Additionally, this specification describes how to encode binary security tokens, a framework for XML-based tokens, and how to include opaque encrypted keys. It also includes extensibility mechanisms that can be used to further describe the characteristics of the tokens that are included with a message. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.1	SOAP is a protocol specification for invoking methods on servers, services, components and objects. SOAP codifies the existing practice of using XML and HTTP as a method invocation mechanism. The SOAP specification mandates a small number of HTTP headers that facilitate firewall/proxy filtering plus an XML vocabulary that is used for representing method parameters, return values, and exceptions." {DevelopMentor} SOAP consists of three parts: an envelope that defines a framework for describing what is in a message and how to process it, a set of encoding rules for expressing instances of application-defined data types, and a convention for representing remote procedure calls and responses. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>



Standard Name	Description/Reason for Use
Organization for the Advancement of Structured Information Standards (OASIS) - ebRIM OASIS – ebXML Registry Information Model v2.1	The Registry Information Model provides a blueprint or high-level schema for the ebXML Registry. Its primary value is for implementers of ebXML Registries. It provides these implementers with information on the type of metadata that is stored in the Registry as well as the relationships among metadata Classes. The Registry information model: a) Defines what types of objects are stored in the Registry; b) Defines how stored objects are organized in the Registry. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) - ebMS OASIS/ebXML Messaging Services Specifications v2.1	Defines a Message Service protocol for reliable Business-to-Business data interchange. ebMS v2.1 adds quality of service features on top of transfer protocols such as HTTP and SMTP. Key qualities of service features include guaranteed delivery and nonrepudiation of receipt. ebMS v2.1 can reliably transfer any data type including XML, X12, EDIFACT, or binary data between two parties over the Internet. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) -ebRS OASIS – ebXML Registry Services Specifications v2.1	The ebXML Registry provides a set of services that enable sharing of information between interested parties for the purpose of enabling business process integration between such parties based on the ebXML specifications. The shared information is maintained as objects in a repository and managed by the ebXML Registry Services defined in this document. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
World Wide Web Consortium (W3C) Web Services Description Language (WSDL) v1.1	WSDL is an XML-based language that provides a model for describing Web services. It is also an XML-based service description on how to communicate using web services. The WSDL defines services as collections of network endpoints, or ports. WSDL specification provides an XML format for documents for this purpose. For more information visit <a href="http://www.w3.org">www.w3.org</a>

## 4.2 GAPS WHERE THERE ARE NO STANDARDS

This section describes gaps in standards. Gaps occur in the following two cases, where HITSP has:

- Identified requirements derived from the context that have no standards that meet all tiers of HITSP criteria to merit selection for that context
- Identified a single standard that encompasses and singly fulfills a set of tightly-coupled standards from the given context, yet is lacking in fulfilling one or more of the tightly-coupled requirements

The gap is only relative to the specific Quality event. Recommended resolutions were developed through a series of steps including the Technical Committee's initial recommendations, cross team validation of the gap, provisional recommendations and peer review by the team.

The table below identifies the Use Case events and known associated gaps, along with the recommended resolutions.



**Table 4.2-1 Use Case Events and Associated Gaps**

Event Code	Event Description	Identified Gaps	Recommended Resolution
6.1.1, 7.1.1	Receive listing of defined measures & abstraction guidelines	Need a terminology, taxonomy, and definition for exclusions	Work with HITEP to establish a common terminology/taxonomy and definition for exclusion. May need to refer to SDOs
6.1.1, 7.1.1	Receive listing of defined measures & abstraction guidelines	Lack of standardization for the expression of a measurement	Until this is defined it is expected that the measure is communicated and manually interpreted and implemented as is done today Work with the Collaborative for Performance measure integration into EHRs. This group is developing a prototype for the measure specification using XML
6.1.1, 7.1.1	Receive listing of defined measures & abstraction guidelines	Measures need to define derivation for accurate implementation	Refer to Measure Department Organizations (MDOs)
6.1.2, 7.1.2	Perform and document patient care	This is a gap with respect to the Use Case for presumptive diagnoses	Semantic Interoperability referral to the Foundation Committee regarding presumptive diagnosis needs to be completed as it will address the presumptive diagnosis segment / requirement in this section  Panel constraint – anything in the DX is assumed to be a defined diagnosis rather than a presumptive diagnosis
6.1.4, 7.1.4	6.1.4 Discharge patient 7.1.4 Healthcare encounter ends	Coded claim data (e.g. discharge diagnosis) is not typically available until well after discharge. – not a standards gap, but a process gap	Addressed by the feedback process of the Use Case
7.1.5	7.1.5 Merge administrative data with EHR data and manual extraction of patient data	Provider may have limited insured and may not have a lot of claims data to merge in (e.g. VA, DOD)	Implementation issue not standards
6.1.1, 7.1.1	Receive listing of defined measures & abstraction guidelines	No standard for expressing defined measures and abstraction guidelines	Leverage Arden Syntax, GLIF, GELLO; OWL, ISO Common Logic, Pending HL7 Report standard
6.1.8, 7.1.8	Transmit patient level quality information	Standardized terminology for allergies to medication, drug intolerances and other allergies is needed as well as the elements or accompanying information (e.g. nature of reaction, severity or reaction, and source of info)  In addition agreement is needed on distinctions among allergies, intolerances, side-effects, sensitivity responses, adverse effects and other similar reactions  Tolerance, adverse events, side effects, sensitivity reaction	ISO TS Adverse events pending  Some SNOMED mapping for some adverse event/side effect terminologies under way  Tolerance definitions not available (for quality typically medication allergen for exclusion) International Harmonization Committee (MedDRA) WHO terminology Recommend harmonization and development of coded terminology



Event Code	Event Description	Identified Gaps	Recommended Resolution
6.1.8, 7.1.8	Transmit patient level quality information	History-enrollment trial is difficult to capture at the appropriate level of precision in ICD9-CM 'v' codes and in SNOMED-CT	Refer gap resolution to NCVHS
6.1.8, 7.1.8	Transmit patient level quality information	Medication-outpatient order filled: If the EHR gets back a fulfillment notification from the pharmacy, then the data may be made available to the analyzer through RDS pharmacy treatment dispense message: HL8 O13.. The EHR would typically receive an NCPDP fulfillment and store it in the EHR. This is currently a workflow/implementation gap in many environments for processing	Refer to HITEP for measure developers for alternate concept specification
6.1.8, 7.1.8	Transmit patient level quality information	Gap in concept representation for optout-other reason (no med/proc/study) such as medical judgment. SNOMED-CT is a potential to be used leveraging the 'unable to accept order'; Clinical note is possible as an observation. ICD-9 V codes may also be used	Request that Structured measures include only codified reasons
6.1.8, 7.1.8	Transmit patient level quality information	Procedure-inpatient (end/closure) - The measures need to determine which element to use to specify the end of the procedure. Potentially derived element from procedure start time and procedure minutes (HL7)	HITEP Referral. MDO needs to be able to express the rule in the terms of the data elements supplied in these messages. There may be multiple ways of calculating the result and each of these ways needs to be specified in the MDO rule (use AND/OR). This will be input to Structured Measure Definitions
6.1.8, 7.1.8	Transmit patient level quality information	"Comfort level only" is inconsistently defined and applied, requires standardization for equal application of measures and exclusion criteria. Referred to HITEP	Refer to Measure Developers, SDOs, and quality data sources
6.1.1, 6.1.8, 7.1.1, 7.1.8	Receive listing of defined measures & abstraction guidelines Transmit patient level quality information	Possible gap for exclusion coding (CPT II <sup>14</sup> codes have been generated to do this)	Need to check with insurance council for exclusion listings. We need to determine whether or not this is suitable for expressing exclusions
6.1.1, 7.1.1	Receive listing of defined measures & abstraction guidelines	Measure definitions needed to specify precisely what defines a patient of interest using coded terminology. Some measures include this, others need further specificity	This specification will assume as a pre-condition clearly defined measures. Requirement will be communicated to the Measure Department Organizations (MDOs)

<sup>14</sup> 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.



Event Code	Event Description	Identified Gaps	Recommended Resolution
6.1.1, 6.1.8, 7.1.1, 7.1.8	Receive listing of defined measures & abstraction guidelines Transmit patient level quality information	Severity gap (e.g. severity for systolic dysfunction) which must be expressed in context of the severity being assessed	Need SNOMED Evaluation for whether there are codes that would be applicable and how to use these Refer to list of measures provided for concepts required For those not in SNOMED, request that they be added
6.1.1, 6.1.8, 7.1.1, 7.1.8	Receive listing of defined measures & abstraction guidelines Transmit patient level quality information	Discharge instructions is a potential gap where measure does not specify the codified content or to express required instruction	The measure should specify the coded values
6.1.1, 6.1.8, 7.1.1, 7.1.8	Receive listing of defined measures & abstraction guidelines Transmit patient level quality information	Orders are ill-defined for both lab and procedure ordered. Need a standard model so that each vendor can map to standardized mechanism to capture the procedure ordered data element	Referred to Foundations Committee (does not address procedure ordered – see consultation gap below) May need to refer to the Foundations Committee (pending further analysis)
6.1.1, 6.1.8, 7.1.1, 7.1.8	Receive listing of defined measures & abstraction guidelines Transmit patient level quality information	Verbal orders are not captured electronically	May need to refer to measure developers or SDOs
6.1.1, 6.1.8, 7.1.1, 7.1.8	Receive listing of defined measures & abstraction guidelines Transmit patient level quality information	ICNP is not in SNOMED CT	Recommend that ICNP and SNOMED CT work together to harmonize
6.1.1, 6.1.8, 7.1.1, 7.1.8	Receive listing of defined measures & abstraction guidelines Transmit patient level quality information	Standards are able to manage the death indicator, but there is a gap in the process to reliably collect and transmit this data element. Hospital outpatient clinics and Emergency Departments may use ADT A^03 to indicate death of outpatients. In the ambulatory setting there is usually no clear standard electronic record of death. The HL7 death indicator exists but is not currently part of workflow in the ambulatory setting	This will be a matter of training. If there is a demographic resource (e.g. PIX - could be a PDQ message); If Vital Health Statistics resource is available; QED might be used against this resource to access the reason(problem) for death. Vital Health Statistics could be instantiated as a Patient Demographic Supplier
6.1.8, 7.1.8	Transmit patient level quality information	CDA document to move patient level data	Consider IHE Medical Summary or constrain a Medical Summary. Conduct additional analysis on possible metadata requirements



Event Code	Event Description	Identified Gaps	Recommended Resolution
6.1.5, 7.1.5	6.1.5 Augment EHR data with manual extraction of patient data (may also occur prior to discharge) 7.1.5 Merge administrative data with EHR data and manual extraction of patient data	Gap for electronic capture of "consult ordered"; there are many ways to determine this information, but no good standard identified. For instance Consult result with appropriate components (e.g. an eye exam with appropriate components – retinopathy; provides a dx ICD can help, but may not be sufficient). Procedures may be an indication of consultation  Need to manage the status of all referrals and orders	The consultation and communication process is too granular to be measurable  Explore incorporation of communication transaction notification
6.1.2, 7.1.2	Perform and document patient care	This is a gap with respect to the Use Case. Semantic Interoperability referral to the Foundation Committee regarding presumptive diagnosis needs to be completed as it will address the presumptive diagnosis segment / requirement in this section	Assumption included that problem list will contain only items with a higher level of assurance
6.1.8, 7.1.8	Transmit patient level quality information	Recommend to LOINC, SNOMED CT, and CPT to develop AND harmonize a suitable coded value set to express order test name and code values	Referred to Foundations Committee
6.1.8, 7.1.8	Transmit patient level quality information	Opt-out is generally a free-text report or field	Refer to ANSI for SDO action
6.1.9, 6.3.3, 7.1.9, 7.3.3	Receive and validate preview report of quality measures; provide corrections if required; Transmit preview report of hospital-level quality measurement for validation/correction	There is no standardization for the communication of aggregated measure results. The TC has been unable to identify efforts under way in this area in either industry or standards	Refer to ANSI for SDO action
6.1.9, 6.3.3, 7.1.9, 7.3.3	Receive and validate preview report of quality measures; provide corrections if required; Transmit preview report of hospital-level quality measurement for validation/correction	Gap in measurement and process with respect to attribution	Refer to HITEP / NQF / ONC for policy consideration.





Event Code	Event Description	Identified Gaps	Recommended Resolution
All	All	Definition of measures Where the definition is not clear, the results of analysis will be inconsistent	Need to roadmap HITEP/HITSP interaction and request preliminary work for data dictionary, measure definitions to contribute to the structured measurement development efforts for latter release  NOTE: Other reasons for opt out – under the assumption that historical data will become more available to quality measurement system, coding practice and computation rules need to be incorporated into the quality measurement specifications from the Measure Department Organizations (MDOs). Coding practices may also need to be encouraged to better reflect codes available that would represent historical clinical details of interest to the quality measurement

### 4.3 STANDARD OVERLAPS

This section describes the instances where there are overlaps among standards for the Use Case. The overlap is only relative to the specific Use Case event. Overlaps refer to instances wherein some of the requirements are met by multiple standards. Recommended resolutions were developed through a series of steps including the Technical Committee's initial recommendations, cross Technical Committee validation of the overlap, provisional recommendations and peer review by the Technical Committee's.

The table below presents the identified overlaps and the respective resolution plans.

**Table 4.3-1 Standard Overlaps**

Event Code	Event Description	Standard Overlap	Recommended Resolution
6.1.8, 7.1.8	Transmit patient level quality information	Discipline-recognized point-of-care user interface terminologies	Discipline-recognized point-of-care user interface terminologies may be used for end systems. Harmonization of these terminologies is needed and should be accelerated  SNOMED CT to be used for interoperability transactions
6.1.8, 7.1.8	Transmit patient level quality information	Role term is used in various standards differently.	Refer to SDOs for harmonization
6.1.1, 7.1.1	Receive listing of defined measures & abstraction guidelines	Arden Syntax, GLIF, GELLO, OWL, ISO Common Logic	Refer for evaluation and harmonization



Event Code	Event Description	Standard Overlap	Recommended Resolution
6.1.5, 7.1.5	6.1.5 Augment EHR data with manual extraction of patient data (may also occur prior to discharge) 7.1.5 Merge administrative data with EHR data and manual extraction of patient data	UN Standard product and services code – Coalition for healthcare e-standards; overlaps with LOINC possible	Pending further review



## 5.0 TECHNICAL IMPLEMENTATION

### 5.1 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.

#### 5.1.1 CONFORMANCE CRITERIA

In order to claim conformance to the specification, an implementation must satisfy all the requirements and mandatory statements listed in the HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must be constrained as specified in Table 3.1.2-1, and implement all of the required actors from Table 3.2.3-1, within the scope, subset or implementation option that is selected from Section 5.1.2 below.

Claims of conformance to this specification must be made using the following language:

This product conforms to HITSP's Quality Interoperability Specification, available at [www.hitsp.org](http://www.hitsp.org).

#### 5.1.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification can be implemented for individual business actors defined in the Interoperability Specification. An implementation claiming conformance to a specific business actor from the Interoperability Specification shall support all of the requirements associated to that business actor as described in Table 3.2.3-1.

This means that **for each implemented business actor**:

1. All Required or Conditionally Required technical actors listed for the business actor shall be supported as specified in the associated construct
2. Optional technical actors listed for the business actor may be supported as specified in the associated construct
3. All Required or Conditionally Required transactions and content subsets listed for each implemented technical actor assigned to the business actor shall be supported as specified in the associated construct
4. Optional transactions and content subsets listed for each implemented technical actor assigned to the business actor may be supported as specified in the associated construct

Implementers of this Interoperability Specification who follow the principles listed above are being provided a level of implementation flexibility, while maintaining interoperability.



### 5.1.3 TEST METHODS

HITSP relies on the conformance test methods, test tools and other test-related material produced by, or under the auspices, of standards developers, profiling organizations and implementation guide producers as part of its collaborative implementation testing effort. Efforts to produce conformance test methods, tools, etc. may be internal to the organization or provided by an external organization.

An HIT Implementation Testing Web Site has been developed in collaboration with HITSP, NIST, CCHIT, and ONC to advance conformance and interoperability testing capabilities. This Web Site provides HIT implementers with the necessary resources to support and test their implementation of standards-based health systems. A link to the Web Site can be found on [www.hitsp.org](http://www.hitsp.org).



## 6.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

### 6.1 DESCRIPTION OF STANDARDS

The following table contains descriptions of the standards that are referenced by this Interoperability Specification.

**Table 6.1-1 Description of 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 <a href="http://www.ama-assn.org">www.ama-assn.org</a>
American Society for Testing and Materials (ASTM) Standard Guide for Electronic Authentication of Health Care Information: # E1762-95(2003)	Defines a document structure for use by electronic signature mechanisms, describes the characteristics of an electronic signature process. Defines minimum requirements for different electronic signature mechanisms. Defines signature attributes for use with electronic signature mechanisms, describes acceptable electronic signature mechanisms and technologies. Defines minimum requirements for user identification, access control, and other security requirements for electronic signatures, and outlines technical details for all electronic signature mechanisms in sufficient detail to allow interoperability between systems supporting the same signature mechanism. For more information visit <a href="http://www.astm.org">www.astm.org</a>
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 <a href="http://www.cms.gov">www.cms.gov</a>
Digital Imaging and Communications in Medicine (DICOM) - Part16: Content Mapping Resource	The Digital Imaging and Communications in Medicine (DICOM) standard was created by the National Electrical Manufacturers Association (NEMA) to aid the distribution and viewing of medical images, such as CT scans, MRIs and ultrasound. This Part specifies the DICOM Content Mapping Resource (DCMR) which defined templates, context groups and vocabulary codes used in the DICOM Standard. For more information visit <a href="http://medical.nema.org">http://medical.nema.org</a>



Standard	Description
European Telecommunications Standards Institute (ETSI) Technical Specification TS 101 903: XML Advanced Electronic Signatures (XadES)	Extends the IETF/W3CXML-Signature Syntax and Processing specification [XMLDSIG] into the domain of non-repudiation by defining XML formats for advanced electronic signatures that remain valid over long periods and are compliant with the European Directive. This includes evidence as to its validity even if the signer or verifying party later attempts to deny (repudiates) the validity of the signature. An advanced electronic signature aligned with this document can, in consequence, be used for arbitration in case of a dispute between the signer and verifier, which may occur at some later time, even years later. For more information, visit <a href="http://www.etsi.org">www.etsi.org</a>
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 <a href="http://www.itl.nist.gov">www.itl.nist.gov</a> .  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 <a href="http://www.cancer.gov/cancertopics">www.cancer.gov/cancertopics</a>



Standard	Description
Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008	The Healthcare Permission Catalog provides the necessary content for creating interoperable roles facilitating inter-organizational communications and information sharing among healthcare organizations and their business partners. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) Version 2.5 <sup>15</sup>	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. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) Version 2.5/2.5.1	The HL7 Version 2.5 and 2.5.1 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, 4, 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. They are also used in HL7 order messages. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
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. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications RCMR_RM010001 - Data Consent	The Data Consent RMIM captures the data and associations needed to (1) record or report a consumer's consent or dissent to authorize the access, collection, use, or disclosure of personally identifiable information; (2) convey a provider's request or intent to override a patient's recorded consent or dissent; (3) convey a type of consent directive associated with a privacy policy; or (4) to record or report a consumer's consent directive, which is to be applied to future access, collection, use or disclosure of personally identifiable information. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>

<sup>15</sup> HITSP references HL7 V2.5.1 messaging for lab results reporting and HL7 V2.5 for other messages. Future maintenance work will move toward referencing a single HL7 version across HITSP documents.





Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a)	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. Section 10, Cross-Enterprise Document Sharing facilitates the registration, distribution and access across health enterprises of patient electronic health records. 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. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b)	The Cross-Enterprise Document Sharing-B Profile (XDS.b) supplement provides a new implementation choice for the Cross-Enterprise Document Sharing (XDS) Integration Profile based on use of the Web Services and ebXML Reg/Rep standards that is consistent with current developments and best practices in the industry. For more information visit <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement [ITI-18]	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 Registry Stored Query Transaction Trial Implementation Supplement specifies an IHE transaction that provides optimization and implementation simplification. This supplement is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement	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 trial implementation version of the XCA Supplement to the ITI-TF, rev. 4.0 Final Text, specifies the IHE transactions that support access between communities in a manner compatible with the XDS Integration profile. This supplement is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Patient Demographics Query (PDQ) Integration Profile	Provides ways for multiple distributed applications to query a central patient information server for a list of patients, based on user-defined search criteria, and retrieve a patient's demographic (and, optionally, visit or visit-related) information directly into the application. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>



Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement - ITI-25 Notification of Document Availability (NAV) Jun 28, 2005	<p>The capability for automation of critical workflows used in healthcare has been greatly advanced by the introduction of the Cross-Enterprise Document Sharing Integration Profile. However, without point-to-point notification of document availability, these workflows still require manual interactions between parties using document sharing.</p> <p>The Notification of Document Availability Integration Profile (NAV) introduces a mechanism allowing notifications to be sent point-to-point to systems and users within an affinity domain, eliminating the need for manual steps or polling mechanisms. This basic mechanism is only intended to facilitate the common part of a large range of workflows related to notifying a remote party (user or system) that one or more documents have been registered in an XDS Registry and may be retrieved if the notified party wishes. For further information, visit <a href="http://www.ihe.net">www.ihe.net</a></p>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 2006-2007 Trial Implementation Supplement Cross-enterprise Document Reliable Interchange (XDR)	<p>This Supplement to the IHE IT Infrastructure Technical Framework provides a generic, standards based mechanism for conveying a set of medical documents in a point-to-point networked based communication. The current version of the XDR is specified in the XDR Trial Implementation Supplement to the ITI-TF, rev. 4.0, which is consistent with IHE XDS.b Supplement in term of document entry metadata. For more information visit <a href="http://www.ihe.net/technical_framework">www.ihe.net/technical_framework</a>.</p> <p>NOTE: off-line mode transaction expected to be updated once standards are available for Web Services Off-line</p>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Patient Identifier Cross-Referencing Integration Profile (PIX)	<p>The Patient Identifier Cross-referencing Integration Profile (PIX) is targeted at healthcare enterprises of a broad range of sizes (hospital, a clinic, a physician office, etc.). It supports the cross-referencing of patient identifiers from multiple Patient Identifier Domains via the following interactions: 1)The transmission of patient identity information from an identity source to the Patient Identifier Cross-reference Manager. 2) The ability to access the list(s) of cross-referenced patient identifiers either via a query/response or via update notification.</p> <p>By specifying the above transactions among specific actors, this integration profile does not define any specific enterprise policies or cross-referencing algorithms. By encapsulating these behaviors in a single actor, this integration profile provides the necessary interoperability while maintaining the flexibility to be used with any cross-referencing policy and algorithm as deemed adequate by the enterprise.. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a></p>



Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Audit Trail and Node Authentication (ATNA) Integration Profile	Audit Trail and Node Authentication (ATNA) establishes the characteristics of a Basic Secure Node. It describes the security environment (user identification, authentication, authorization, access control, etc.) assumed for the node so that security reviewers may decide whether this matches their environments. It defines basic auditing requirements for the node. It defines basic security requirements for the communications of the node using TLS or equivalent functionality. It establishes the characteristics of the communication of audit messages between the Basic Secure Nodes and Audit Repository nodes that collect audit information. This integration profile has been designed so that specific domain frameworks may extend it through an option defined in the domain specific technical framework. Extensions are used to define additional audit event reporting requirements, especially actor specific requirements. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Consistent Time (CT) Integration Profile	The Consistent Time Integration Profile (CT) provides a means to ensure that the system clocks and time stamps of the many computers in a network are well synchronized. This profile specifies synchronization with a median error less than 1 second. This is sufficient for most purposes. The current version of the ITI-TF, rev. 4.0 for Final Text, specifies the IHE CT Integration Profile, and other transactions defined and implemented as of August 22, 2007. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise User Assertion (XUA)	The Cross-Enterprise User Assertion Profile (XUA) provides a means to communicate claims about the user identity of an authenticated principal (user, application, system...) in transactions that cross enterprise boundaries. To provide accountability in these cross enterprise transactions there is a need to identify the requesting user in a way that the receiver can make access decisions and proper audit entries. The XUA Profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the entities, and others that may have chosen to use a third party to perform the authentication. The latest version of the IHE framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement Volume 3 – Document Digital Signature (DSG) Content Profile	Specifies the use of digital signatures for documents that are shared between organizations. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) 2007 – 2008 Supplement, Retrieve Form for Data Capture (RFD)	<p>The Retrieve Form for Data Capture Profile (RFD) provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the retrieval of forms from a form source, display and completion of a form, and return of instance data from the display application to the source application.</p> <p>The profile relies upon XForms technology to support negotiation between the form display and form provider systems, so that iterative exchanges can deal with issues like form selection, completion of a series of forms, partial completion of forms, returning to forms partially filled out in earlier sessions. RFD also supports archiving a copy of the completed form</p>



Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0	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. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) – Trial Implementation	The Basic Patient Privacy Consents (BPPC) profile provides a mechanism to record the patient privacy consent(s), a method to mark documents published to XDS with the patient privacy consent that was used to authorize the publication, and a method for XDS Consumers to use to enforce the privacy consent appropriate to the use. This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. systems). There are two key parts of the profile: 1) It provides a document content specification for capturing a patient acknowledgement of a privacy consent policy or policies. 2) It describes the method by which XD* Actors can enforce the privacy policies determined by the document confidentialityCode related to the patient privacy consents. The latest version of specification is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Volume 1, Revision 3.0 2007 - 2008	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 <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 3.0, 2007 - 2008, Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile	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 <a href="http://www.ihe.net">www.ihe.net</a>



Standard	Description
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). For more information visit <a href="http://www.cms.hhs.gov">www.cms.hhs.gov</a> .  Note: While ICD-10 is not deployed in US installations, we recognize the need to move toward new releases of coded values
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. For more information visit <a href="http://www.cdc.gov/nchs">www.cdc.gov/nchs</a>
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 <a href="http://www.ihtsdo.com">www.ihtsdo.com</a>
International Organization for Standardization (ISO) Health informatics -- Pseudonymisation, Unpublished Technical Specification # 25237	Health Informatics – Pseudonymisation. Approved as a Technical Specification March, 2007. For more information visit <a href="http://www.iso.org">www.iso.org</a>
International Organization for Standardization (ISO) Health Informatics -- Pseudonymization, Unpublished Technical Specification # 25237	Health Informatics – Pseudonymization. Approved as a Technical Specification March, 2007. Visit <a href="http://www.iso.org">www.iso.org</a> for more information
Internet Engineering Task Force (IETF) Network Time Protocol (Version 3) Specification, Implementation and Analysis, "Request for Comment" (RFC) # 1305, March, 1992	Describes the Network Time Protocol (NTP): the mechanisms to synchronize time and coordinate time distribution in a large, diverse internet operating at rates from mundane to lightwave. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>
Internet Engineering Task Force (IETF) Simple Network Time Protocol (SNTP) Version 4, "Request for Comment" (RFC) # 2030, October, 1996	Describes the Simple Network Time Protocol (SNTP) Version 4, which is an adaptation of the Network Time Protocol (NTP). SNTP can be used when the ultimate performance of the full NTP implementation is not needed or justified. When operating with current and previous NTP and SNTP versions, SNTP Version 4 involves no changes to the NTP specification or known implementations, but is rather a clarification of certain design features of NTP. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>



Standard	Description
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. For more information visit <a href="http://www.loinc.org">www.loinc.org</a>
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 <a href="http://www.nlm.nih.gov">www.nlm.nih.gov</a>
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 <a href="http://www.nubc.org">www.nubc.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.1, 1.2	SOAP is a protocol specification for invoking methods on servers, services, components and objects. SOAP codifies the existing practice of using XML and HTTP as a method invocation mechanism. The SOAP specification mandates a small number of HTTP headers that facilitate firewall/proxy filtering plus an XML vocabulary that is used for representing method parameters, return values, and exceptions." (DevelopMentor) SOAP consists of three parts: an envelope that defines a framework for describing what is in a message and how to process it, a set of encoding rules for expressing instances of application-defined data types, and a convention for representing remote procedure calls and responses. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) v2.0 OASIS Standard; ITU-T X.1141	SA SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) WS-Federation Web Services Federation Language (WS- Federation), Version 1.1, December 2006	Defines mechanisms to allow different security realms to federate, such that authorized access to resources managed in one realm can be provided to security principals whose identities and attributes are managed in other realms. This includes mechanisms for brokering of identity, attribute, authentication and authorization assertions between realms, and privacy of federated claims. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>



Standard	Description
Organization for the Advancement of Structured Information Standards (OASIS) WS-Trust Version 1.3, March 2007	Defines extensions that build on [WS-Security] to provide a framework for requesting and issuing security tokens, and to broker trust relationships. Defines Security Token Service (STS) model for security tokens including requesting, issuing, renewing, canceling and validating. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) eXtensible Access Control Markup Language (XACML), ITU-T Recommendation X.1142, February 2005	The Organization for the Advancement of Structured Information Standards (OASIS) standards group developed the eXtensible Access Control Markup Language (XACML) as a language to express and evaluate access decisions. The XACML technical specification includes a profile for RBAC using XACML that complies with the ANSI RBAC standard. The HL7 RBAC Permission Catalog provides a standard vocabulary that can be used for cross-enterprise access control. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
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 <a href="http://aurora.regenstrief.org">aurora.regenstrief.org</a>





## 7.0 CHANGE HISTORY

The following sections provide the history of changes made to this document.

### 7.1 DECEMBER 5, 2007

The changes in this cycle address the following comments:

2331, 2332, 2333, 2334, 2335, 2336, 2338, 2339, 2340, 2341, 2342, 2343, 2346, 2348, 2349, 2419, 2421, 2422, 2518, 2519, 2520, 2522, 2523, 2528

The full text of the comments along with the Technical Committee's disposition can be reviewed on the [HITSP Public Web Site](#).

### 7.2 DECEMBER 13, 2007

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

### 7.3 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. Please refer to the underlying constructs for specific changes to standards

### 7.4 AUGUST 27, 2008

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



RELEASED FOR IMPLEMENTATION

