

HITSP Quality Interoperability Specification

HITSP/IS06



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1.0 INTRODUCTION

This Healthcare Information Technology Standards Panel (HITSP) document is divided into Requirements, Design and Capabilities sections which may be used by analysts, architects and implementers. Analysts might use this document to refer to the requirements of a particular Harmonization Request. Architects and system implementers might refer to this document as the top level architectural specification for a system design while software developers will use the Interoperability Specification (IS) as a source of requirements for interoperable information exchange.

The following table details specific sections of this Interoperability Specification template and how specific sections of this document are targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 1-1 Reader's Guide for Interoperability Specification

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements	2.1 Synopsis of Requirements	Policy Managers Policy Analysts Executive Leadership	Used to provide an overview (using a scenario-based approach) of the requirements applicable to this document. Readers should start here to learn more about what specific requirements this IS is intended to address
	2.2 System Description	Architects Business Analysts Policy Analysts Program Managers	The systems assigned to the system roles (as defined in the HITSP Capabilities used by this IS) are identified and described here. Readers can learn which systems have been included as part of this HITSP IS
Section 3.0 Design Specification	3.1 Capabilities Used	Architects Business Analysts Development Team	For each HITSP Information Exchange Requirement (IER) identified in Section 2.0, a corresponding HITSP Capability is associated and mapped. A reader can review how specific HITSP Capabilities meet information exchange needs. A diagram is also provided to show the interchange of data among systems identified in this IS
	3.2 Capability Orchestration	Architects Development Team	The core of the design in the IS is documented here. This solution shows orchestration of Capabilities to meet the specific HITSP information exchange requirements in Section 3.1. The design also identifies conditions and constraints, as well as any content subsets specific to the solution
Section 4.0 Capability Gaps	4.0 Capability Gaps	Business Analysts Development Team Architects	Gaps specific to Capabilities used as part of this IS are reviewed in this section to determine why specific information exchange requirements may not yet be met or defined. Readers should check this section to track the progress of gap resolution
Section 5.0	5.1 Provisional Exchange Content Description	Architects	Supporting information is provided for HITSP exchange content that is identified as provisional (due to gaps identified in the previous section)
	5.2 Provisional Data Requirements	Architects	Supporting information is provided for HITSP data requirements that are associated with provisional exchange content identified in Section 5.1
	5.3 Harmonization Request Traceability	Architects Business Analysts	A complete mapping of information exchange requirements to functional requirements is provided in this section. Readers can trace IER's to underlying Harmonization Request events and actions (in those instances where a Use Case exists) or to functional requirements defined as part of an official standards Harmonization Request

1.1 INTEROPERABILITY SPECIFICATION OVERVIEW

This HITSP Quality Interoperability Specification is designed to enable interoperable, electronic quality (eQuality) monitoring. This represents a paradigm shift from a primarily manual abstraction environment to a more efficient electronic environment aligned with information managed within the



electronic health record. This Interoperability Specification specifies standards to enable efficiencies through standard electronic exchanges. The specification provides selected standards to allow quality measures to address the information captured electronically while encouraging the capture, analysis and aggregation of that information consistently for performance reporting and concurrent care improvement. Much of the quality measurement performed in the current environment is based upon manual abstraction requiring significant time and effort to compile and submit data for quality analysis. This Interoperability Specification is intended to support migration toward an electronic quality measurement paradigm that will support more timely and efficient process through standardization of interoperable information flows needed to support quality measurement.

In this release of the Interoperability Specification, we provide the standards required to support the encoding of the data types identified by the Health Information Technology Expert Panel (HITEP) as the framework for a Quality Data Set (QDS). As exemplars, the Interoperability Specification evaluated three measure sets that include sixteen inpatient measures provided to HITSP by the Centers for Medicare and Medicaid Services (CMS). These measure sets cover care provided in the Emergency Department (ED), care for patients with stroke and care to prevent the development of Venous Thromboembolism (VTE). These measures are addressed as exemplars to show how to interoperably encode a quality measure specification as well as clinical data captured during usual healthcare delivery for use in calculating the provider's performance as defined by the encoded quality measure specification. In so doing, the process should 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.

The HITSP Quality Interoperability Specification is based on the Office of the National Coordinator for Health Information Technology (ONC) 2007 Quality Use Case and subsequent Harmonization Request from CMS. This Interoperability Specification 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 used to support certain measures that are not fully 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 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. Federal, State, Local, and business policies 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 DOCUMENT SCOPE

The design leverages existing HITSP Capabilities and Data Dictionary. The analysis for this Interoperability Specification is based upon data elements required to support data types identified by the Health Information Technology Expert Panel (HITEP) for a Quality Data Set (QDS), to support any potential measure. Also included in the design is a provisionally selected standard, the HL7 Healthcare Quality Measure Format (HQMFM) V1.0, which will enable the communication of eMeasures. This standard will remain provisionally selected by HITSP until such time as has passed



DSTU ballot in HL7 and is published as a DSTU. Until such time, it will remain as an 'intended for use' standard.

There is a significant variation in practice and insufficient standards to express measures and results, requiring harmonization and analytical effort to establish a consistent approach for the Interoperability Specification. The modeling is expected to support any potential measure. The design is intended to enable electronic communication of patient level quality data. This effort will further inform requirements for structured specification of quality measures and aggregate report. There is an accompanying HITSP Security and Privacy Technical Note (HITSP/TN900) that specifically enables communication of three measure sets provided to HITSP by CMS: Stroke, VTE, and ED. These measures are provided in HITSP/TN900 Security and Privacy as exemplars.

There are significant re-tooling efforts that are involved in converting measures designed for manual abstraction to leverage the electronic Quality Measurement interoperability described in this specification. Such re-tooling involves review and testing by measure developers and endorsement organizations. This Interoperability Specification does not address the evaluation of evidence, feasibility and impact of measures, all of which are part of the measure endorsement process. Retooling is intended only for establishing the appropriate vocabulary and record representation of the data required by the measure, and not the evidence or intent of the measure. Evaluation of measure results using existing methods and 'retooled' measures is highly important during the transition from abstracted to electronic measurement. Such effort is outside the HITSP scope. For example, the National Quality Forum (NQF) will maintain a process for evaluation of electronic measures as part of their consensus development and maintenance processes. Evaluation studies are recommended to evaluate the impact on quality measurement initiatives and public reporting.

There are also considerations required for changes in EHR workflows that will be needed to support extraction and assembly of clinical data based upon the measure specification. The impact of each data type must be address with respect to

- The source data collection
- The addition of data elements not yet supported by EHRs
- Different trigger conditions to ensure that complete information has been collected, which may occur at any time during an encounter or external to the encounter workflow

It is clear that these activities are beyond the scope of HITSP, but these process re-engineering activities must be taken into consideration in the implementation of this Interoperability Specification.

Due to gaps identified within this Interoperability Specification, further specification for capabilities for sending Aggregated Quality Measure Data are deferred until the associated standards gap is filled. Additional updates to this specification will require continued collaboration with the NQF who will work with measure developers for standardization and greater completeness of measure specification.

1.3 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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1.4 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material. HITSP-maintained reference documents can be retrieved from the [HITSP Web Site](#).

Table 1-2 Reference Documents

Reference Document	Document Description
HITSP Acronyms List	Lists and defines the acronyms used in this document



HITSP Quality Interoperability Specification

Released for Implementation

20100125 V2.0

Reference Document	Document Description
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents

1.5 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.

1.5.1 CONFORMANCE CRITERIA

For an implementation to claim conformance to a HITSP Interoperability Specification, it must be implemented in its entirety or within a limited scope or subset as defined within the 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 this Interoperability Specification, and implement all of the required interfaces within the scope, subset or implementation options as described.

1.5.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

HITSP may define the permissibility for system scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. The selected scope, subset or options shall specifically be stated, and implementations must include all requirements within the selected scope, subset or options to claim conformance.

For this Interoperability Specification, conformance may be declared by a participating system for any Capability provided that all declared constraints, conditions and requirements imposed by the Capability and its referenced HITSP constructs are satisfied.

1.5.3 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 and Support](#) Web Site has been developed in collaboration with HITSP, the National Institute of Standards and Testing (NIST), the Certification Commission for Healthcare Information Technology (CCHIT), and the Office of the National Coordinator for Health Information Technology (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.



2.0 REQUIREMENTS

Section 2.0 identifies the requirements from the Harmonization Request for which information exchanges are necessary. The following table details how this section and other sections of the document are targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 2-1 Reader's Guide for Section 2.0

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements	2.1 Synopsis of Requirements	Policy Managers Policy Analysts Executive Leadership	Used to provide an overview (using a scenario-based approach) of the requirements applicable to this document. Readers should start here to learn more about what specific requirements this Interoperability Specification is intended to address
	2.2 System Description	Architects Business Analysts Policy Analysts Program Managers	The systems assigned to the system roles (as defined in the Capabilities used by this IS) are identified and described here. Readers can learn which systems have been included as part of this Interoperability Specification

2.1 SYNOPSIS OF REQUIREMENTS

The following table describes the Information Exchange Requirements needed to accomplish the Harmonization Request for which information exchange is necessary.

Table 2-2 Description of Information Exchange Requirements

Information Exchange Requirement Number (IER)	Description
IS06-IER1	Send EC 106 Measure Specification
IS06-IER2	Request & Response EC 66 Value Sets
IS06-IER3	Request Existing Patient Data EC 105 Patient-Level Quality Data
IS06-IER4	Pre-Populate Form for EC 105 Patient-Level Quality Data
IS06-IER5	Request & Response EC 106 Measure Specification
IS06-IER6	Request & Response EC 32 Summary of Care
IS06-IER7	Request & Response EC 48 Encounter Summary
IS06-IER8	Request & Response EC 28 Emergency Encounter Summary
IS06-IER9	Request & Response EC 30 Consent Document Component
IS06-IER10	Send EC 105 Patient-Level Quality Data
IS06-IER11	Publish/Register EC 105 Patient-Level Quality Data
IS06-IER12	Publish/Register EC 30 Consent Document Component
IS06-IER13	Request & Response EC 105 Patient-Level Quality Data
IS06-IER14	Send EC 144 Aggregate Measure Report
IS06-IER15	Request & Response EC 23 Patient Demographics
IS06-IER16	Request & Response EC 24 Pseudo-identity

Table 2-3 lists and describes the major subdivisions of a Harmonization Request, called Scenarios.

The events and actions within this Harmonization Request relate to the measurement, feedback and reporting of quality information related to care delivery performance. While the Harmonization Request portrays two scenarios - the Hospital-based Care and Clinician described in Table 2-3 below the scenarios have the same interoperability requirements. As such, these two scenarios have been considered jointly in this Specification to minimize duplicate content.



Table 2-3 Description of Scenarios

Scenario Name	Scenario Description
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. This 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, such as physician offices, emergency departments, and surgical settings

2.1.1 INFORMATION EXCHANGE REQUIREMENTS FOR HOSPITAL-BASED CARE AND CLINICIAN SCENARIOS

The following Information Exchange Requirements Table summarizes the relationship between the Exchange Action, Exchange Content, and the Initiating and Responding Systems. These exchange requirements are presented in terms of the implementation variants described in Section 3.2.2 for simplification purposes.

NOTE: The term 'Data Assembly' is used in this table and throughout this document to refer to the process of compiling all of the patient-level clinical attributes needed to report out a given quality measure.

Table 2-4 Hospital-Based Care and Clinician Scenario Information Exchange Requirements¹

Information Exchange Requirement Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IS06-IER1	Send	EC 106 Measure Specification	Performance Measurement Information Resource	Data Assembly Assistant, Quality Measurement Processing Entity	
IS06-IER2	Request & Response	EC 66 Value Sets	Data Assembly Assistant	Health Information Exchange (HIE), Performance Measurement Information Resource	
IS06-IER3	Request Existing Patient Data	EC 105 Patient-Level Quality Data	Data Assembly Assistant	Electronic Health Record (EHR) System, Health Information Exchange (HIE)	When applicable, policy may require Inclusion of EC 25 Anonymization Instructions and/or EC 26 Nonrepudiation of Origin Data based on local, regional, state, or contractual policies

¹ [NOTE: Data Assembly Assistant may be performed by the EHR, by the HIE, or by the Quality Report Processing Entity]



Information Exchange Requirement Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IS06-IER4	Pre-populate Form	for Patient-Level Quality Data	Data Assembly Assistant	Electronic Health Record (EHR) System, Health Information Exchange (HIE), Quality Measurement Processing Entity	When applicable, policy may require Inclusion of EC 25 Anonymization Instructions and/or EC 26 Nonrepudiation of Origin Data based on local, regional, state, or contractual policies
IS06-IER5	Request & Response	EC 106 Measure Specification	Data Assembly Assistant	Performance Measurement Information Resource	
IS06-IER6	Request & Response	EC 32 Summary of Care	Data Assembly Assistant	Health Information Exchange (HIE)	
IS06-IER7	Request & Response	EC 48 Encounter Summary	Data Assembly Assistant	Health Information Exchange (HIE)	
IS06-IER8	Request & Response	EC 28 Emergency Encounter Summary	Data Assembly Assistant	Health Information Exchange (HIE)	
IS06-IER9	Request & Response	EC 30 Consent Document Component	Data Assembly Assistant	Health Information Exchange (HIE)	When applicable, policy may require Inclusion of EC 25 Anonymization Instructions and/or EC 26 Nonrepudiation of Origin Data based on local, regional, state, or contractual policies
IS06-IER10	Send	EC 105 Patient-Level Quality Data	Data Assembly Assistant	Quality Measurement Processing Entity, Quality Measure and Reporting System	When applicable, policy may require Inclusion of EC 25 Anonymization Instructions and/or EC 26 Nonrepudiation of Origin Data based on local, regional, state, or contractual policies
IS06-IER11	Publish/ Register	EC 105 Patient-Level Quality Data	Data Assembly Assistant	Health Information Exchange (HIE)	When applicable, policy may require Inclusion of EC 25 Anonymization Instructions and/or EC 26 Nonrepudiation of Origin Data based on local, regional, state, or contractual policies



Information Exchange Requirement Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IS06-IER12	Publish/ Register	EC 30 Consent Document Component	Data Assembly Assistant	Health Information Exchange (HIE)	When applicable, policy may require Inclusion of EC 25 Anonymization Instructions and/or EC 26 Nonrepudiation of Origin Data based on local, regional, state, or contractual policies
IS06-IER13	Request & Response	EC 105 Patient-Level Quality Data	Quality Measurement Processing Entity	Health Information Exchange (HIE)	When applicable, policy may require Inclusion of EC 25 Anonymization Instructions and/or EC 26 Nonrepudiation of Origin Data based on local, regional, state, or contractual policies
IS06-IER14	Send	EC 144 Aggregate Measure Report	Quality Measurement Processing Entity	Electronic Health Record (EHR) System, Health Information Exchange (HIE)	
IS06-IER15	Request & Response	EC 23 Patient Demographics	Data Assembly Assistant	Health Information Exchange (HIE)	
IS06-IER16	Request & Response	EC 24 Pseudo-identity	Data Assembly Assistant	Health Information Exchange (HIE)	Where policy requires pseudonymization

2.2 SYSTEM DESCRIPTION

The following table lists Systems involved in the above listed scenarios, and identifies the stakeholders served by those involved systems.

Table 2-5 System Names and Descriptions

System Name	System Description	Stakeholders
Electronic Health Record (EHR) System	The Electronic Health Record (EHR) System is a secure, real-time, point-of-care, patient-centric information resource for clinicians	Healthcare Delivery Organizations, Ancillary Entities, Clinicians, Care Delivery
Health Information Exchange (HIE) System	Health Information Exchange (HIE) System is a multi-stakeholder system 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	Health Information Exchanges



System Name	System Description	Stakeholders
Quality Measure and Reporting System	Systems used by organizations that develop, adopt or endorse clinical quality measures	Multi-Hospital Measurement and Reporting, Joint Commission, CMS, NCQA, Destination Agent/Monitor Agent/Measurement System, payers, Health Insurance Plans (HIPs, Optional), clearinghouses, data warehouses, third party vendor support, associations providing services, Quality Measurement, Reporting Enterprise Certified Agencies, and Patient Safety Organizations
Quality Measurement Processing Entity System	Systems 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 rd party organizations. clearinghouses, data warehouses, third party vendor support, associations providing services, Quality Measurement and Reporting Enterprise Certified Agencies, payers, HIPs (Optional)
Performance Measurement Information Resource	Systems that provide an electronic resource of codified structured quality measures and measure metadata	Consumers, HIM Personnel, Healthcare Payors, Healthcare Purchasers, Health Researchers, Public Health Monitoring System, Quality Organizations, Clinicians, Healthcare Delivery Organizations, Ancillary Organizations, and Certifying/licensing boards
Data Assembly Assistant	System that supports the assembly of patient level quality data from clinical data sources. This may be the EHR, an HIE, a third party, or a Quality Measurement Processing Entity	Healthcare Delivery Organizations, Ancillary Entities, Clinicians, Care Delivery Interface Health Information Exchanges Implementers can be the same organization as the Performance Measure Adopter, or approved 3 rd party organizations. clearinghouses, data warehouses, third party vendor support, associations providing services, Quality Measurement and Reporting Enterprise Certified Agencies, payers, HIPs (Optional)



3.0 DESIGN SPECIFICATION

Section 3.0 identifies the Capabilities used to meet the requirements identified in Section 2.0 Requirements and describes how to orchestrate this set of Capabilities to meet those requirements. The following table details how this section of the document is targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 3-1 Reader's Guide for Section 3.0

Document Section	Section Number	Intended Audience	Information Contained
Section 3.0 Design Specification	3.1 Capabilities Used	Architects Business Analysts Development Team	For each Information Exchange Requirement (IER) identified in Section 2.0, a corresponding Capability is associated and mapped. A reader can review how specific Capabilities meet information exchange needs. A diagram is also provided to show the interchange of data among systems identified in this Interoperability Specification
	3.2 Capability Orchestration	Architects Development Team	The core of the design in the Interoperability Specification is documented here. This solution shows orchestration of Capabilities to meet the specific information exchange requirements in Section 3.1. The design also identifies conditions and constraints, as well as any content subsets specific to the solution.

3.1 CAPABILITIES USED

The table below lists the Capabilities used in this Interoperability Specification, and relates them to the Information Exchange Requirements from Table 2-2 that the Capability satisfies.

Table 3-2 Capabilities Used

Capability	Capability Summary	IERs satisfied
HITSP/CAP119 - Communicate Structured Document	<p>This Capability addresses interoperability requirements that support the communication of structured health data related to a patient in a context set by the source of the document who is attesting to its content. Several document content subsets, structured according to the HL7 CDA standard, are supported by this Capability. The following are examples of the type of structured data that may be used:</p> <ul style="list-style-type: none"> Continuity of Care Document (CCD) HITSP/C32 Emergency Department Encounter Summary HITSP/C28 Discharge Summary (In-patient encounter and/or episodes of care) HITSP/C48 Referral Summary Ambulatory (encounter and/or episodes of care) HITSP/C48 Consultation Notes & History and Physical HITSP/C84 Personal Health Device Monitoring Document HITSP/C74 Healthcare Associated Infection (HAI) Report Document HITSP/C75 <p>Document creators shall support a number of the HITSP specified coded terminologies as defined by specific content subsets specified in this Capability</p>	IS06-IER6 IS06-IER7 IS06-IER8
HITSP/CAP122 - Retrieve Medical Knowledge	<p>This Capability addresses the requirements to retrieve medical knowledge that is not patient-specific based on context parameters. The actual content delivered is not constrained by this Capability; this Capability focuses on providing the mechanism to ask for (query) and receive the medical knowledge</p>	IS06-IER2 IS06-IER17 IS06-IER18



Capability	Capability Summary	IERs satisfied
HITSP/CAP123 - Retrieve Existing Data	This Capability supports queries for clinical data (e.g., common observations, vital signs, problems, medications, allergies, immunizations, diagnostic results, professional services, procedures and visit history)	IS06-IER3
HITSP/CAP129 – Communicate Quality Measure Data	<p>This Capability addresses interoperability to support hospital and clinician collection and communication of patient encounter data to support the analysis needed to identify a clinician or hospital's results relative to an EHR-compatible, standards-based quality measure. Quality measures may include:</p> <ul style="list-style-type: none"> • Patient-level clinical detail from which to compute quality measures. Patient level clinical data are compiled from both the local systems and from longitudinal data available through other sources such as a Health Information Exchange (HIE) • Patient-level quality data based upon clinical detail. The "patient-level quality data reports" are exported from EHRs or quality-monitoring applications at the point of care <p>This Capability may use content anonymization. Pseudonymization, if needed, is supported by HITSP/CAP138-Retrieve Pseudonym. This Capability may use Value Set Sharing</p>	IS06-IER10 IS06-IER11 IS06-IER14 IS06-IER15 IS06-IER13
HITSP/CAP130 - Communicate Quality Measure Specification	This Capability addresses interoperability requirements for an EHR-compatible, standards-based quality measure. In the measure specification, needed patient encounter data elements are identified so they can be extracted from local systems and from longitudinal data available through other sources such as a Health Information Exchange (HIE). The measure specification also includes various sets of exclusion/inclusion criteria to identify which patients to include in calculation of the measure. This Capability may use Value Set Sharing	IS06-IER1 IS06-IER5
HITSP/CAP135 - Retrieve and Populate Form	<p>This Capability addresses interoperability requirements to support the upload of specific captured data (e.g. public health surveillance reportable conditions, healthcare associated infection reporting) to Public Health Monitoring Systems and Quality Organizations Systems. The forms presented may be pre-populated by information provided by the clinical or laboratory information systems to avoid manual re-entry. A number of supplemental information variables may be captured from within the user's clinical information system to improve the workflow and timeliness of required reporting. One or more types of form content may be supported:</p> <ul style="list-style-type: none"> • Pre-population for Public Health Case Reports from Structured Documents using CDA • Pre-population for Quality Data from Structured Documents using CDA • No pre-population content <p>Systems may optionally support the means to retrieve request for clarifications</p>	IS06-IER4



Capability	Capability Summary	IERs satisfied
HITSP/CAP138 - Retrieve Pseudonym	This Capability addresses interoperability requirements to support a particular type of anonymization that both removes the association with a data subject, and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms. This enables a process of supplying an alternative identifier, which permits a patient to be referred to by a key that suppresses his/her actual identification information. The purpose of this Capability is to offer a pseudonymization framework for situations that require the use of specific data without disclosing the specific identity of patients or providers. Pseudo-identifiers are intended to allow accessibility to clinical information, while safeguarding any information that may compromise the privacy of the individual patient or provider. However, unlike anonymization, the alternative identifier key can be used to re-identify the individuals whose data was used	IS06-IER16
HITSP/CAP143 - Manage Consumer Preference and Consents	This Capability addresses management of consumer preferences and consents as an acknowledgement of a privacy policy. This Capability is used to capture a patient or consumer agreement to one or more privacy policies; where examples of a privacy policy may represent a consent, dissent, authorization for data use, authorization for organizational access, or authorization for a specific clinical trial. This Capability also supports the recording of changes to prior privacy policies such as when a patient changes their level of participation or requests that data no-longer be made available because they have left the region	IS06-IER9 IS06-IER-12 IS06-IER-23 IS06-IER-29

The following diagram shows how systems use Capabilities to complete the full IS. The diagram is purposely created to be architecturally neutral. In some settings a given system role within a Capability will be filled by more than one system in the IS. In many settings, one system may implement multiple Capabilities as shown in the diagram. There are many potential combinations of systems using these Capabilities in different architectures as discussed in Section 3.2.2 Implementation Variants. The diagram therefore uses one example that includes all systems.



Figure 3-1 Diagram Showing Capabilities Used Between Systems – Part 1

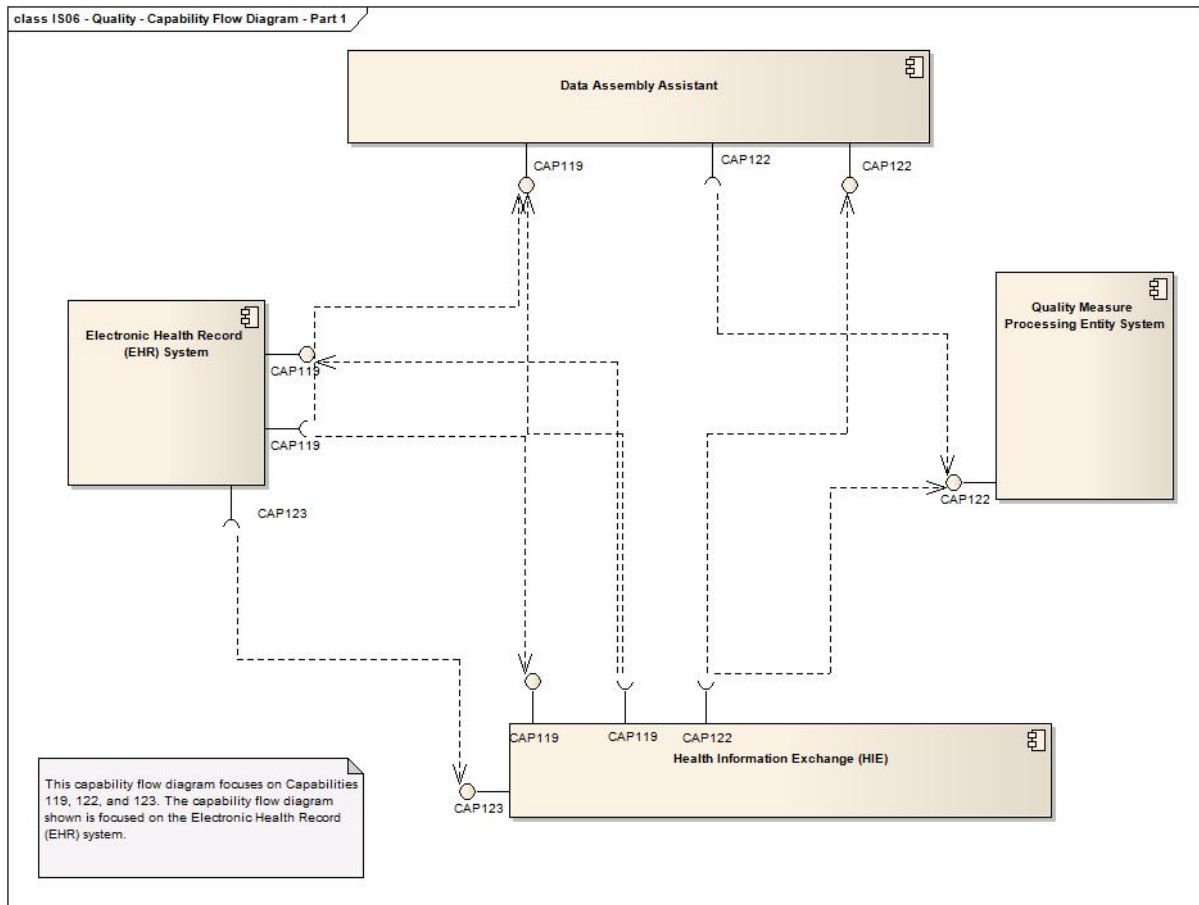


Figure 3-1 shows the capabilities that may be used to assemble quality data from clinical systems. This includes capabilities for querying existing data, sharing documents, and consent management. It also includes services for pseudonymization and value set exchange.



Figure 3-2 Diagram Showing Capabilities Used Between Systems – Part 2

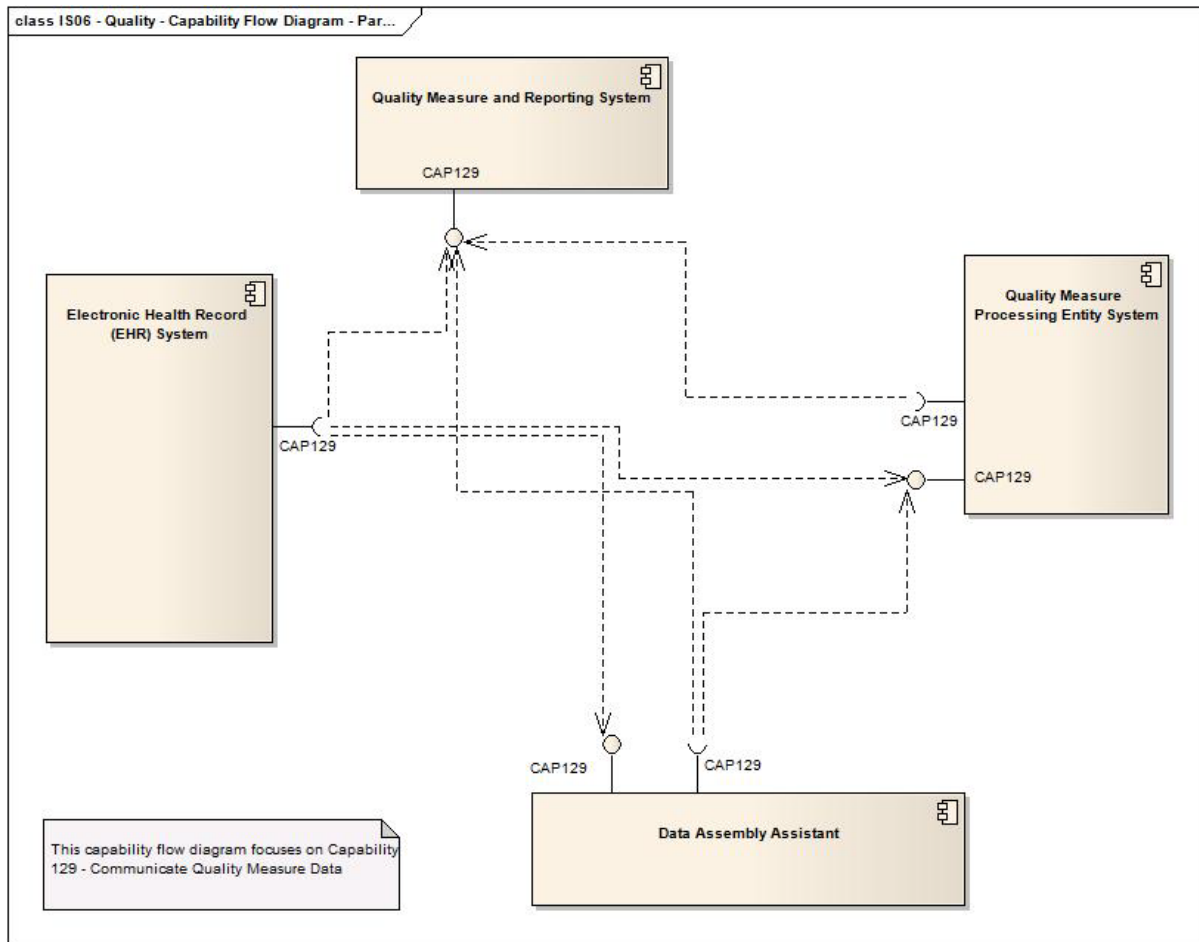


Figure 3-2 shows the use of HITSP/CAP129 Communicate Quality Measure Data for the communication of patient level quality data from either the EHR or from the Data Assembly assistant for processing by the Quality Measure Processing Entity System and the Quality Measure and Reporting System.



Figure 3-3 Diagram Showing Capabilities Used Between Systems – Part 3

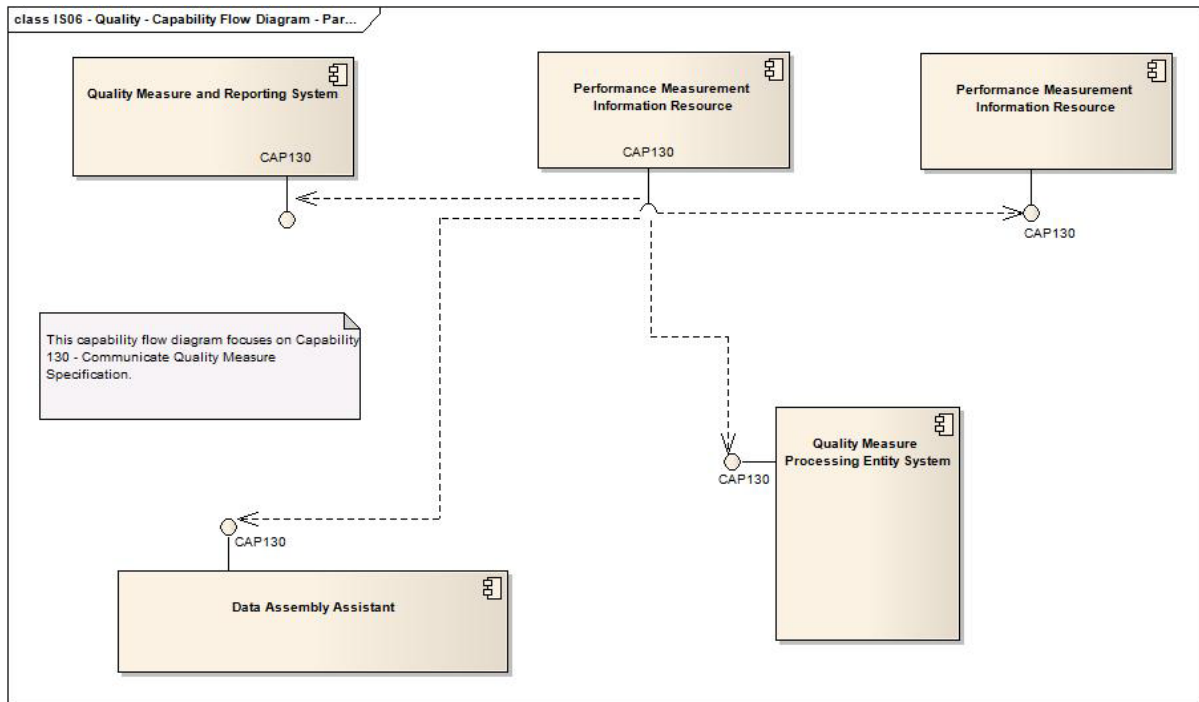


Figure 3-3 shows the use of HITSP/CAP130 Communicate Quality Measure Specification for the communication of Quality eMeasures provided by the Performance Measurement Information Resource to those entities that may be engaged in providing quality measure information.

3.2 CAPABILITY ORCHESTRATION

This section describes how the Capabilities identified above are orchestrated to achieve the aims of the Harmonization Request (such as a Use Case) addressed by this Interoperability Specification. The orchestration identifies Systems that fill the System roles in the Capabilities to achieve the desired data flows.

Table 3-3 lists the orchestration of Capabilities to meet the information exchange requirements described in Section 2.0. Subsets of these Systems perform information exchanges according to one or more of the Capabilities identified in this Specification. The Capabilities are annotated on the diagrams. The in-scope requirements are supported by Capabilities either previously specified by HITSP or new Capabilities introduced in this section. Optionality is expressed as Required (R), Optional (O) or Conditional (C). If the optionality is Conditional, the applicable conditions are given in Table 3-4 below.

Table 3-3 Orchestration of Capabilities by System

System	System Role(s)	System Role Option	Capability	Optionality
Electronic Health Record (EHR) System	Document Source	C[106]	HITSP/CAP119 - Communicate Structured Document	Content: HITSP/C28, HITSP/C32, HITSP/C48, C[103], C[104], C[106], C[112] HITSP/C26: C[109]
	Clinical Data Source	C[106]	HITSP/CAP123 – Retrieve Existing Data	C[103]



System	System Role(s)	System Role Option	Capability	Optionality
	Form Filler	C[106]	HITSP/CAP135 – Retrieve and Populate Form	C[103] C[102] HITSP/C26: C[109]
	Request HL7 Message	C[106]	HITSP/CAP129 – Communicate Quality Measure Data	R Content: HITSP/C34
	Document Source	R	HITSP/CAP143 – Manage Consumer Preference and Consents	R
Health Information Exchange (HIE)	Registry	R	HITSP/CAP119 – Communicate Structured Document	R
	Repository	R	HITSP/CAP119 – Communicate Structured Document	R
	Knowledge Requestor	C[105] C[110]	HITSP/CAP122 – Retrieve Medical Knowledge	R
	Knowledge Resource	C[105] C[110]	HITSP/CAP122 – Retrieve Medical Knowledge	R
	Value Set Repository	O	HITSP/CAP122 – Retrieve Medical Knowledge	R
	Clinical Data Source	O	HITSP/CAP123 – Retrieve Existing Data	C[103]
	Pseudonymization Services	C[101]	HITSP/CAP138 – Retrieve Pseudonym	R
	Person Identification Services	C[101]	HITSP/CAP138 – Retrieve Pseudonym	R
Quality Measure and Reporting System	Document Consumer	R	HITSP/CAP129 – Communicate Quality Measure Data	R: Content HITSP/C105 HITSP/C26: C[109]
	Measure Consumer	R	HITSP/CAP130 – Communicate Quality Measure Specifications	R
Quality Measure Processing Entity System				
	Value Set Consumer	O	HITSP/CAP122 – Retrieve Medical Knowledge	R
	Value Set Repository	O	HITSP/CAP122 – Retrieve Medical Knowledge	R
	Document Source	O	HITSP/CAP129 – Communicate Quality Measure Data	R Content: HITSP/C105
	Document Consumer	C[107]	HITSP/CAP129 – Communicate Quality Measure Data	R Content: HITSP/C105
	Measure Consumer	C[111]	HITSP/CAP130 – Communicate Quality Measure Specifications	R
Performance Measurement Information Resource	Measure Source	R	HITSP/CAP130 – Communicate Quality Measure Specifications	R Content: HITSP/C106 HITSP/C26: C[109]
	Measure Consumer	O	HITSP/CAP130 – Communicate Quality Measure Specifications	R Content: HITSP/C106 HITSP/C26: C[109]



System	System Role(s)	System Role Option	Capability	Optionality
Data Assembly Assistant	Document Consumer	C[108]	HITSP/CAP119 - Communicate Structured Document	Content: HITSP/C32, HITSP/C48, HITSP/C28 C[112] C[103], C[104], C[106] HITSP/C26: C[109]
	Knowledge Requestor	C[105] C[110]	HITSP/CAP122 – Retrieve Medical Knowledge	R
	Value Set Consumer	O	HITSP/CAP122 – Retrieve Medical Knowledge	R
	Value Set Repository	O	HITSP/CAP122 – Retrieve Medical Knowledge	R
	Clinical Data Consumer	C[108]	HITSP/CAP123 – Retrieve Existing Data	C[103]
	Form Manager (Option for CIS supporting form management locally)	O	HITSP/CAP135 – Retrieve and Populate Form	C[103] C[102] HITSP/C26: C[109]
	Form Receiver (Option for CIS supporting form management locally)	C[108]	HITSP/CAP135 – Retrieve and Populate Form	C[103] C[102] HITSP/C26: C[109]
	Form Archiver (Option for CIS supporting form management locally)	O	HITSP/CAP135 – Retrieve and Populate Form	C[103] C[102] HITSP/C26: C[109]
	Respond to HL7 Message	C[108]	HITSP/CAP129 – Communicate Quality Measure Data	Content: HITSP/C34 R
	Measure Consumer	C[110]	HITSP/CAP130 – Communicate Quality Measure Specification	Content: HITSP/C106 HITSP/C26: C[109]
	Patient Identity Source	C[101]	HITSP/CAP138 – Retrieve Pseudonym	R
	Pseudonymization Services	C[101]	HITSP/CAP138 – Retrieve Pseudonym	R
	Document Source	R	HITSP/CAP129 – Communicate Quality Measure Data	Content: HITSP/C105
	Document Consumer	C[108]	HITSP/CAP129 – Communicate Quality Measure Data	Content: HITSP/C105
	Document Source	R	HITSP/CAP143 – Manage Consumer Preference and Consents	R
	Document Consumer	R	HITSP/CAP143 – Manage Consumer Preference and Consents	R

Optionality Legend: “R” for Required, “R2” for Required if Known , “O” for Optional, or “C” for Conditional

Table 3-4 below lists the conditions applicable to the orchestration (see above table) of the Capabilities engaged in this Interoperability Specification.

Table 3-4 Conditions

Condition Code	Condition Description
[101]	There must be at least one system that provides this Capability where pseudonymization is required by policy
[102]	Pre-populate with HITSP/C105, HITSP/C32, HITSP/C28, HITSP/C48



Condition Code	Condition Description
[103]	Alternatives among specific configurations are available to support multiple implementation configurations
[104]	Depending upon the measure the EHR may use HITSP/CAP119 to collect/extract quality data from source systems such as PHR, Lab, (etc.)
[105]	For retrieval of medical knowledge, there is no requirement that data be structured, and it may in fact be unstructured in many cases. However, for Quality eMeasures, the response is anticipated to return a C106 conformant payload. No structure is specified at this time for the request for an eMeasure
[106]	SHALL support at least one of the cited methods of supplying clinical source data for quality measurement
[107]	SHALL support at least C105 Document Consumer or be grouped with a data assembly assistant
[109]	Required where nonrepudiation required by policy
[110]	This may be optionally used to deliver HITSP/C106 content. Other ways of transmitting HITSP/C106 are permissible (e.g., email) as this is not patient-specific content
[111]	Where access control required by policy
[112]	HITSP Clinical Summaries including HITSP/C28, HITSP/C32, HITSP/C48 shall conform to 'Summary Document Quality Subset'

3.2.1 CONTENT SUBSETS

Content subsets are appropriate subsets of the data content supported by the Capability that may be sent by the system and/or received in a specific information exchange. There may be no relevant subsets identified.

3.2.1.1 SUMMARY DOCUMENT "QUALITY SUBSET"

This subset identifies content modules that contain data of relevance to Quality Measures. Where HITSP Clinical Summary Documents such as HITSP/C32, HITSP/C48, or HITSP/C28 are provided for patient-level quality data assembly, the content modules below should be provided if known to optimize the utility for quality measurement assembly purposes.

Table 3-5 Creator Medication and Immunization History Subset Content Modules

Content Modules	Optionality
Comments	R2
Healthcare Provider	R2
Immunization	R2
Information Source	R2
Medications (Ordered)	R2
Medications Administered	R2
Discharge Medications Ordered	R2
Personal Information	R
Condition	R2
Encounter	R
Family History	R2
History of Past Illness	R2
History of Present Illness	R2
Review of Symptoms	R2
Problem List	R2
Chief Complaint	R2
Allergy/Drug Sensitivity	R2
List of Surgeries	R2
Procedure	R2
Result (Laboratory)	R2
Diagnostic Test Results	R2
Medical Equipment	R2

Optionality Legend: "R" for Required, "R2" for Required if Known, "O" for Optional, or "C" for Conditional

Additional Clinical Summary content modules may be present, but are not required in this subset. Within the context of this subset, the content consumer is not required to recognize or process such "additional" content modules.



All entries shall contain associated codes as indicated by the data elements in the Appendix.

3.2.2 IMPLEMENTATION VARIANTS

This specification is intended to support multiple implementation architectures. Figure 3-4 contains all implementation variants, each of which is shown individually in a separate diagram. The intent is to highlight the required transactions. Transactions are required only between different systems. Multiple functions performed within one system can be managed locally.

Figure 3-4 Implementation Variants

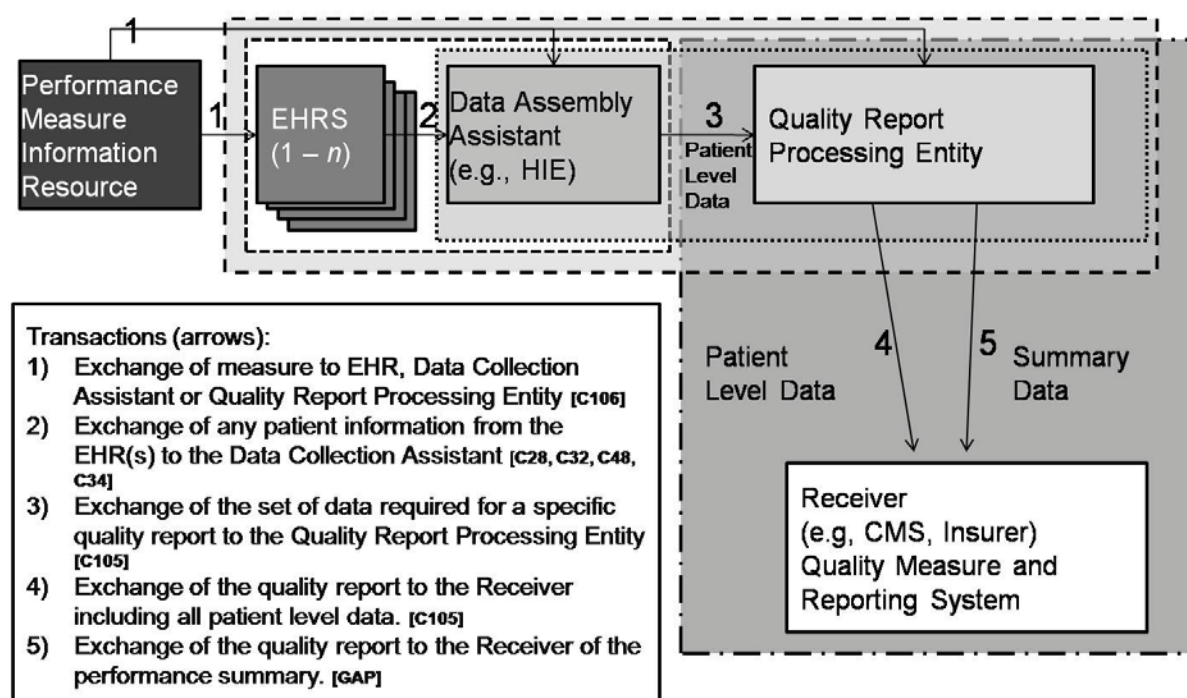


Figure 3-5 indicates data flows that may be used in the multiple implementation variants. The boxes within this diagram indicate the Systems in this Interoperability Specification. The numbered arrows represent the high level communications of exchange content within the system. The Data Assembly Assistant is a data manager for a variety of EHRs and EHR sub-systems that compiles all of the patient-level clinical attributes needed to report out a given quality measure. An HIE can represent a Data Assembly system when that function is separate from the EHRs.

The variations are primarily in Data Assembly and in Measure Analysis. Below, we describe groupings that allow data collection and analytical services of a given implementation to be provided locally or by a third party. These are examples of common ways that entities may be grouped for functionality. These examples describe:

- Those functions that are unique
- Exchanges that are performed between different entities performing these functions
- Edge-to-edge communications – while multiple functions may be performed inside a single organization, all of the functions must occur

This leads to the following implementation variants:

Data Assembly Variants



- Implementation Variant 1: Different entities perform the Data Assembly, EHR functions, and Quality Report Processing functions
- Implementation Variant 2: The same entity performs the Data Assembly and EHR functions
- Implementation Variant 3: The same entity performs the Data Assembly and Quality Report Processing Functions
- Implementation Variant 4: The same entity performs the Data Assembly, EHR functions, and Quality Report Processing functions

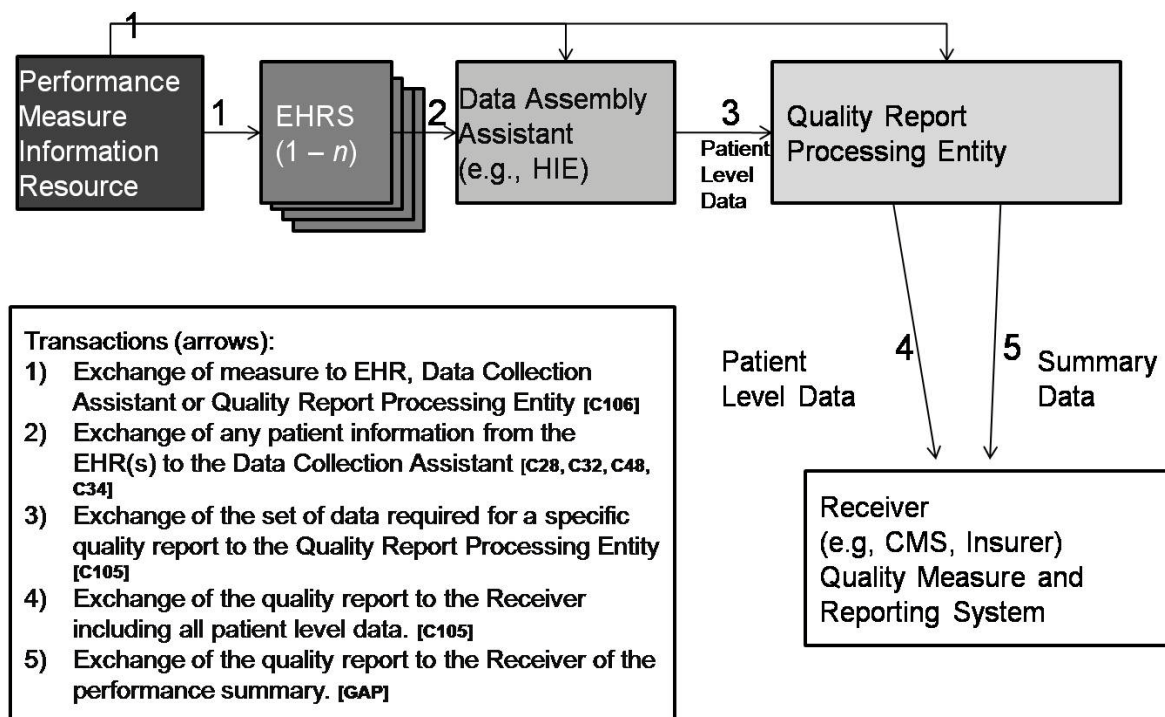
While any of these variants are possible, at least one of the three systems (EHR, HIE, Quality Report Processing Entity) must provide the Data Assembly. The eMeasure data must be available from the Performance Measurement Information Resource to the system performing the Data Assembly.

Data Analysis Variant

- The variants above all indicate that a separate entities performs the Quality Report Processing functions and the Quality measurement analysis functions as the first Data Analysis variant and are not described further below
- Implementation Variant 5: The same entity performs the Quality Report Processing functions and the Quality Measurement analysis functions. This implementation variant may apply to all of the Data Assembly variants listed above:

While both of these variants are possible, at least one of the two systems (Quality Report Processing Entity, Quality Measure and Reporting System) must provide the Analysis.

Figure 3-5 Implementation Variants – Variant 1



Implementation Variant 1: Different entities perform the Data Assembly, EHR functions, and Quality Report Processing functions

In Implementation Variant 1 depicted in Figure 3-7 Implementation Variants – Variant 3

5 above, each of functions is performed by a different entity. The HIE or other third party retrieves clinical data from the EHR, performs the Data Assembly and sends the HITSP/C105 Patient-Level Quality Data (QRDA) to the Quality Report Processing Entity

The information flow is as follows:

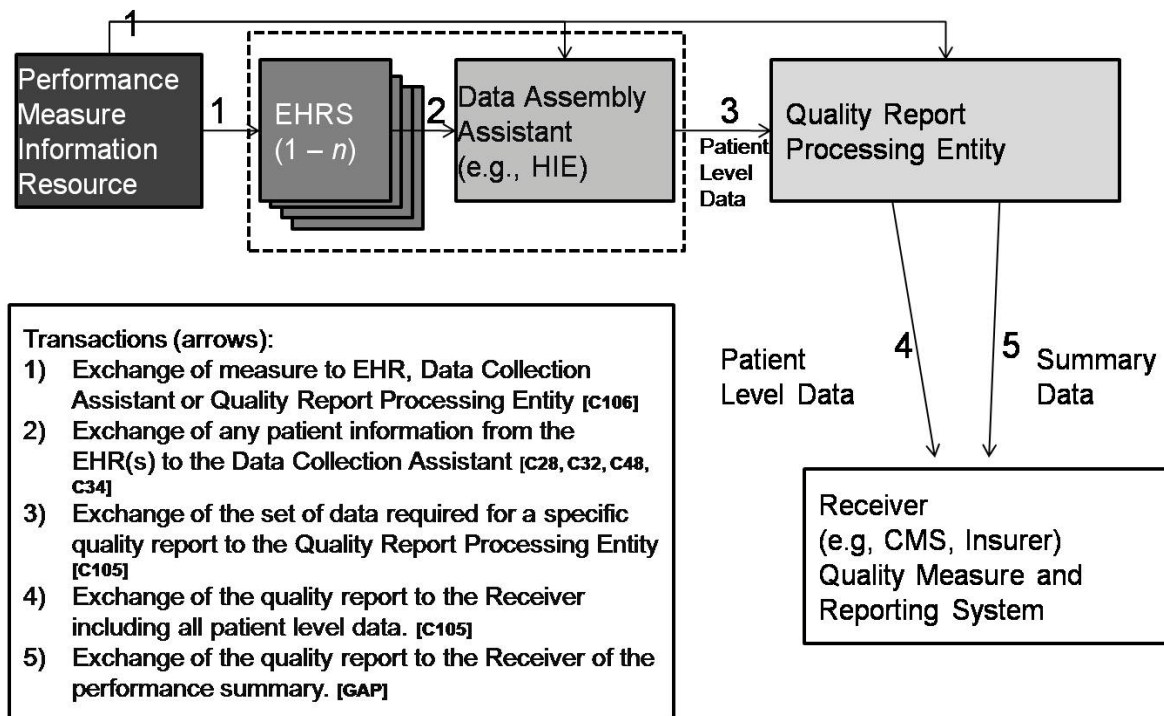
- The eMeasure is communicated to the HIE (or other third party), and Quality Report Processing Entity using HITSP/CAP130 Communicate Quality Measure Specification for exchanging the HITSP/C106 Measurement Criteria Component. See Arrow (1)
- The HIE (or other third party), may leverage any of HITSP Capabilities, such as, HITSP/CAP119 (Pre-Populated from HITSP documents HITSP/C28, HITSP/C32, HITSP/C48), HITSP/CAP123 to query for existing clinical data from another system, HITSP/CAP135 (Pre-Populated from HITSP documents HITSP/C28, HITSP/C32, HITSP/C48), or HITSP/CAP129 (messaging using HITSP/C34) to enable communication of source clinical data from EHRs. While any of these transactions are optional, at least one of these must be supported. See Arrow (2)
- Data Assembly Assistant sends QRDA to Quality Report Processing Entity Leveraging CAP129 (HITSP/C105 Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA) See Arrow (3)
- The Processing entity sends the QRDA patient/summary level to Quality Measure and Reporting System using HITSP/CAP129 (HITSP/C105 Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA), Summary Data GAP). See Arrows (4,5)

NOTE: Feedback to the EHR of summary data may be provided by the Quality Measure and Reporting System or the Quality Report Processing Entity. This is a defined gap and not shown in Figure 3-2.

An example of this Implementation Option is where the HIE provides the Data Assembly Assistant as an exchange added value to the provider of the data.



Figure 3-6 Implementation Variants – Variant 2



Implementation Variant 2: The same entity performs the Data Assembly and EHR functions

In Implementation Variant 2 depicted in Figure 3-6 above, the EHR performs all of the Data Assembly and produces a HITSP/C105 Patient-Level Quality Data (QRDA) Document directly. In the second variant dashed lines (small dashes), the EHRs perform the activities of the Data Assembly Assistant as a single technical resource. The Quality Report Processing Entity and the Receiver remain unique

The information flow is as follows:

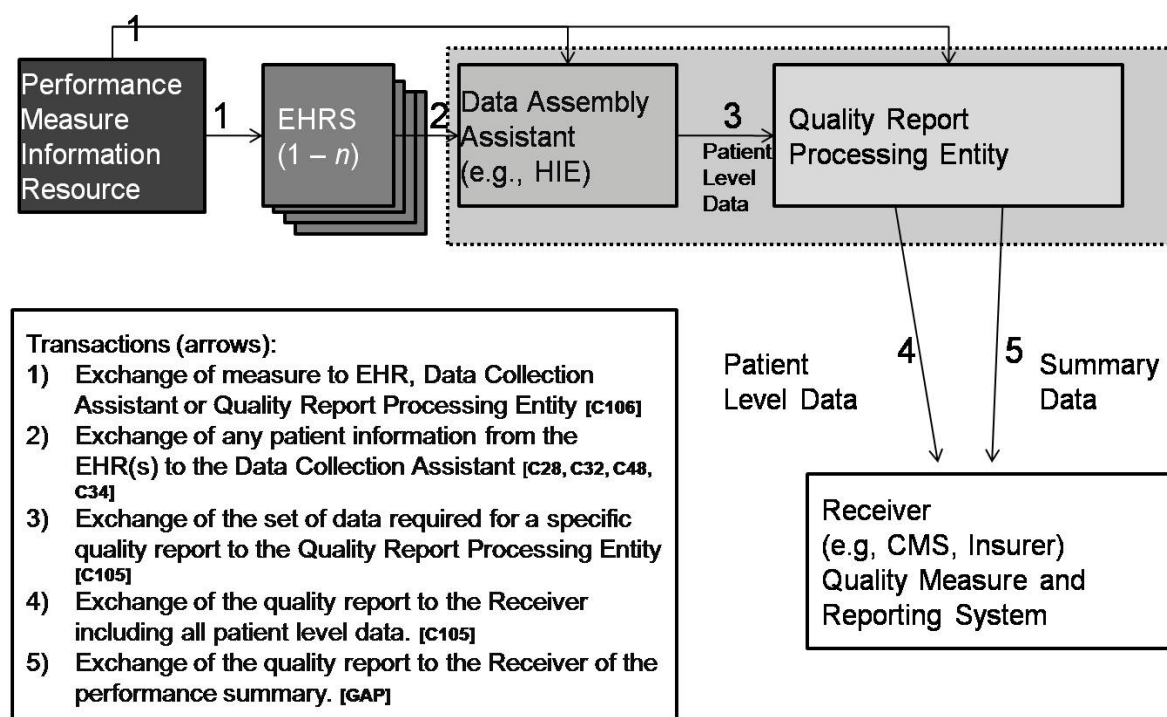
- The eMeasure is communicated to the EHR using HITSP/CAP130 for exchanging the HITSP/C106 Measurement Criteria Document See Arrow (1)
- The EHR may leverage any of HITSP Capabilities, such as, HITSP/CAP119 (Pre-Populated from HITSP documents HITSP/C28, HITSP/C32, HITSP/C48), HITSP/CAP123 to query for existing clinical data from another system, HITSP/CAP135 (Pre-Populated from HITSP documents HITSP/C28, HITSP/C32, HITSP/C48), or HITSP/CAP129 (messaging using HITSP/C34) to gather and assemble the data to populate the patient level quality data. The EHR produces the HITSP/C105 Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA) and sends the QRDA to the Quality Report Processing entity using HITSP/CAP129. See Arrow (3)
- The Quality Report Processing Entity sends the QRDA patient/summary level to Quality Measure and Reporting System using HITSP/CAP129 (HITSP/C105 Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA), Summary Data GAP). See Arrows (4, 5)

An example of this variant is where an EHR has a Quality Management Utility that supports the Clinical Setting.

NOTE: Feedback to the EHR of summary data may be provided by the Quality Measure and Reporting System or the Quality Report Processing Entity. This is a defined gap and not shown in Figure 3-2.



Figure 3-7 Implementation Variants – Variant 3



Implementation Variant 3: Data Assembly and Quality Report Processing are performed by the same entity

In Implementation Variant 3 depicted in Figure 3-7 above Data Assembly and Quality Report Processing are performed by the same entity. In this, variant the EHRs is a separate entity. The Data Collection Assistant and the Quality Report Processing Entity are managed by the same application and organization. The receiver also remains unique.

The information flow is as follows:

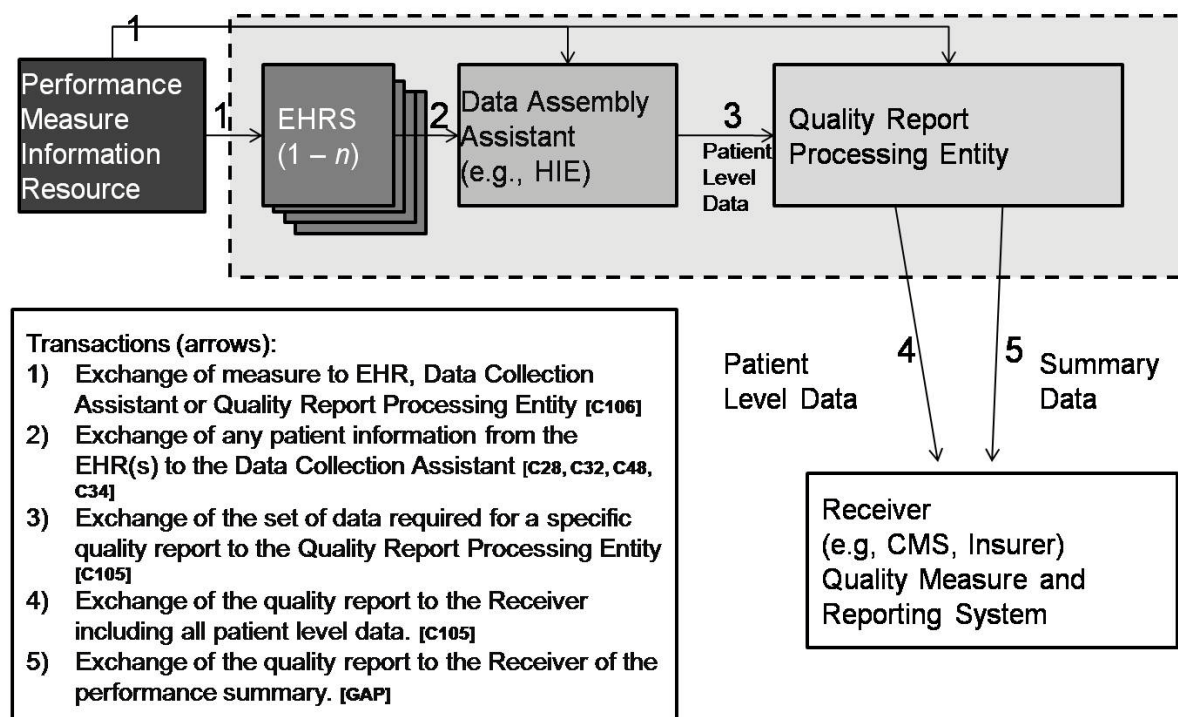
- The eMeasure is communicated to the Quality Report Processing Entity using HITSP/CAP130 Communicate Quality Measure Specification for exchanging the HITSP/C106 Measurement Criteria Component. See Arrow (1)
- The Quality Report Processing Entity may leverage any of HITSP Capabilities, such as, HITSP/CAP119 (Pre-Populated from HITSP documents of HITSP/CAP119 (Pre-Populated from HITSP documents HITSP/C28, HITSP/C32, HITSP/C48), CAP123 to query for existing clinical data from another system, HITSP/CAP135 (Pre-Populated from HITSP documents HITSP/C28, HITSP/C32, HITSP/C48), or HITSP/CAP129 (messaging using HITSP/C34) to enable communication of source clinical data from EHRs. While any of these transactions are optional, at least one of these must be supported. See Arrow (2)
- Data Assembly Assistant sends QRDA to Quality Report Processing Entity Leveraging HITSP/CAP129 (HITSP/C105 Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA). See Arrow (3)
- The Processing entity sends the QRDA patient/summary level to Quality Measure and Reporting System using HITSP/CAP129 (HITSP/C105 Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA), Summary Data GAP). See Arrows (4,5)



NOTE: Feedback to the EHR of summary data may be provided by the Quality Measure and Reporting System or the Quality Report Processing Entity. This is a defined gap and not shown in Figure 3-2.

An example of this Implementation Option is where the Oryx Vendors provide Data Assembly and Data Validation on behalf of the Hospitals. A second example would be where the Data Assembly is provided by a third party data warehouse vendor involved in Quality Measurement.

Figure 3-8 Implementation Variants – Variant 4



Implementation Variant 4: The same entity performs the Data Assembly, EHR functions, and Quality Report Processing functions

In Implementation Variant 4, the same entity performs the Data Assembly, EHR functions, and Quality Report Processing functions. In this fourth variant, the EHRs contains functionality that also performs the Data Assembly Assistant function as well as completing the report calculations and formatting so that it also acts as the Quality Report Processing Entity. The Receiver remains unique.

The information flow is as follows:

- The eMeasure is communicated to the Quality Report Processing Entity using HITSP/CAP130 Communicate Quality Measure Specification for exchanging the HITSP/C106 Measurement Criteria Document. See Arrow (1)
- The Data Assembly functions of the entity may leverage any of HITSP Capabilities, such as, HITSP/CAP119 (Pre-Populated from HITSP documents of HITSP/CAP119 (Pre-Populated from HITSP documents HITSP/C28, HITSP/C32, HITSP/C48), CAP123 to query for existing clinical data from another system, HITSP/CAP135 (Pre-Populated from HITSP documents HITSP/C28, HITSP/C32, HITSP/C48), or HITSP/CAP129 (messaging using HITSP/C34) to enable communication of source clinical data from EHRs. Where this data are all available within the system, none of the capabilities may apply.

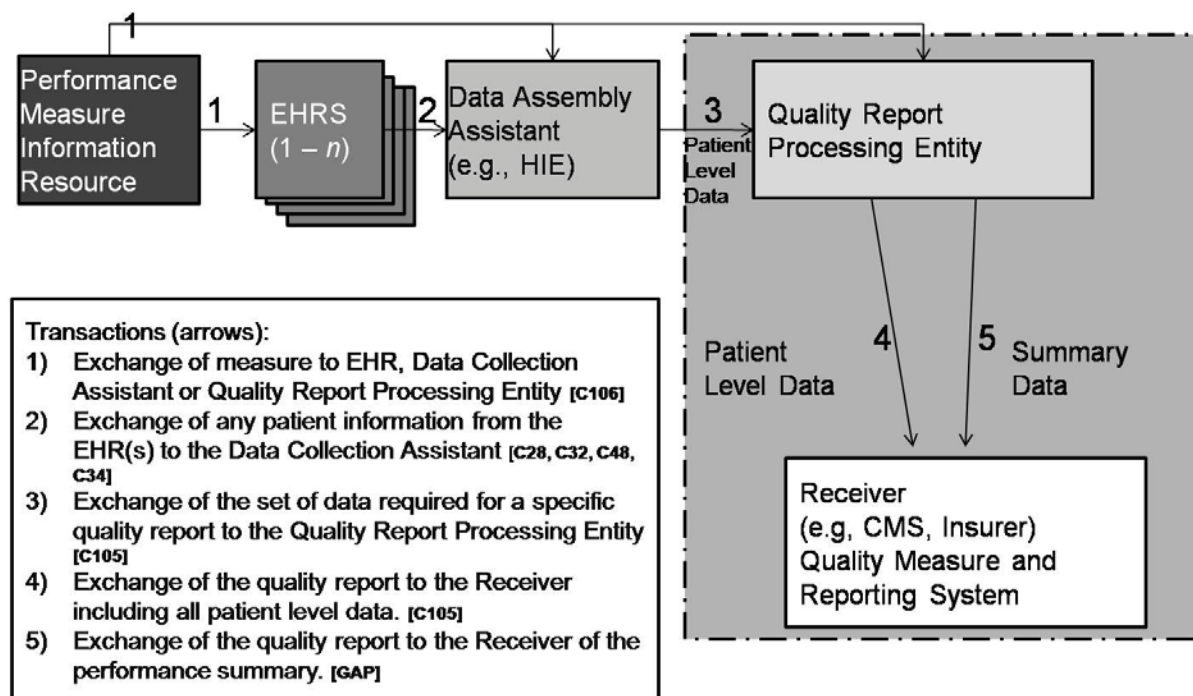


- The entity sends the QRDA patient/summary level to Quality Measure and Reporting System using HITSP/CAP129 (HITSP/C105 Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA), Summary Data GAP). See Arrows (4,5)

NOTE: Feedback to the EHR of summary data may be provided by the Quality Measure and Reporting System or the Quality Report Processing Entity. This is a defined gap and not shown in Figure 3-2.

An example of this Implementation Option is where the EHR that is approved for submission directly to CMS (Receiver). It is the EHR's own registry that manages the assembly and compilation of the report to be sent.

Figure 3-9 Implementation Variants – Variant 5



Implementation Variant 5: Data assembly and Quality Measure/Reporting are performed by the same entity

In Implementation Variant 6 depicted in Figure 3-8 above, The Data Assembly is performed by the Quality Measure and Reporting System. The Quality Report Processing Entity only supports HITSP/C105 Patient-Level Quality Data (QRDA) documents and does not offer any Data Collection Services. In this variant, the EHRs and Data Assembly Assistant are unique and the Quality Report Processing Entity function is performed by the Receiver. Alternately, the EHRs and Data Assembly Assistant may also be combined in one product.

The information flow is as follows:

- The eMeasure is communicated to the and Quality Report Processing Entity using HITSP/CAP130 Communicate Quality Measure Specification for exchanging the HITSP/C106 Measurement Criteria Document and others depending upon the Data Assembly variants 1-3. See Arrow (1)
- Data are assembled according to Data Assembly variants 1-3. See Arrow (2)



- Quality Report Processing Entity Receives QRDA Leveraging HITSP/CAP129 (HITSP/C105 Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA). CAP Arrow (3)

NOTE: Feedback to the EHR of summary data may be provided by the Quality Measure and Reporting System or the Quality Report Processing Entity. This is a defined gap and not shown in Figure 3-2.

An example of this Implementation is where the insurer collects patient level data and performs analysis internally.

NOTE: Policy and agreements may specify that verification and data quality analysis processes be conducted and/or certified

Table 3-6 lists a number of general constraints applicable to this specification. They include assumptions, a number of pre-conditions and post-conditions as well as external trigger events that play a critical role in implementing this specification.

Table 3-6 Orchestration Constraints

Number	Constraint	Type of Constraint
IS06-C[301]	For retrieval of medical knowledge using HITSP/CAP122, there is no requirement that data be structured, and it may in fact be unstructured in many cases. However, for Quality eMeasures, the response is anticipated to return a HITSP/C106 conformant payload. No structure is specified at this time for the request for an eMeasure	Assumption
IS06-C[302]	Attribution will be fairly applied by measure receivers	Assumption
IS06-C[303]	The EHR is a resource for structured data	Assumption
IS06-C[304]	Security and access protections will assure that data are confidential and protected until approved for publication	Assumption
IS06-C[306]	An EHR is in place and able to communicate patient-level quality data or is able to send electronic data to a processing entity to prepare the patient-level quality data	Assumption
IS06-C[307]	Indication of re-calculation is a manual, non-electronic process	Assumption
IS06-C[308]	Policies for sharing data are defined in agreements	Pre-conditions
IS06-C[309]	Policy Methodology for risk-adjustment for public reporting is identified determined by measure developers	Pre-conditions
IS06-C[310]	Public Reporting relation to internal risk management is identified	Pre-conditions
IS06-C[311]	Public Reporting security/access protection is defined	Pre-conditions
IS06-C[312]	Policy for refuting the data prior to publication of comparative results is identified	Pre-conditions
IS06-C[313]	An evidence-based, standard method for attribution of performance measures to clinicians and providers is required	Pre-conditions
IS06-C[314]	Measures of quality healthcare delivery, whether structural, process or outcome related that are based on evidence and the participants of both edges of the communication have agreed to utilize these measures for a number of decision points. These may be used for state, local, and business quality measures as well as national	Pre-conditions
IS06-C[315]	Clearly defined measures are available. (e.g., AQA for Heart Failure set of measures)	Pre-condition
IS06-C[316]	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	Pre-conditions
IS06-C[317]	An audit of queries may be assessed for added efficiency	Post-conditions
IS06-C[318]	IHE Patient Encounter Management Profile	Trigger



Number	Constraint	Type of Constraint
IS06-C[319]	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	Trigger
IS06-C[320]	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	Trigger
IS06-C[321]	Additional Patient level Quality Data are required for the measure	Trigger
IS06-C[322]	Additional Historical Patient level Quality Data are required for the measure	Trigger
IS06-C[323]	Patient level measurement data requires pseudonymization by policy	Trigger
IS06-C[324]	Aggregate data are ready for provider review	Trigger
IS06-C[325]	Validation error identified and patient level data are corrected and update sent for measurement calculation	Trigger
IS06-C[326]	Provider approves public release	Trigger
IS06-C[327]	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	Trigger

3.2.3 CONSTRAINTS ON REQUIRED CAPABILITIES

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

Table 3-7 Additional Constraints on Required Capabilities

Number	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
IS06-C[401]	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/CAP129 - Communicate Quality Measure Data	Information Content	Pre-condition	Required to protect the confidentiality of the patients whose personal health information is sent for quality measurement analysis
IS06-C[402]	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/CAP129 - Communicate Quality Measure Data	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



Number	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
IS06-C[403]	Patient level data sent to a recipient and recorded in the shared registry must be anonymized unless otherwise permitted through legal and out-of-band arrangements	HITSP/CAP129 - Communicate Quality Measure Data	Information Content	Pre-condition	Required to protect the confidentiality of the patients whose personal health information is sent for quality measurement analysis
IS06-C[404]	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/CAP129 - Communicate Quality Measure Data	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
IS06-C[405]	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/CAP129 - Communicate Quality Measure Data HITSP/C105 - Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA)	Documents should contain some machine-readable content	Pre-condition	Used to assure machine-consumable information for large volume information exchange and processing
IS06-C[406]	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/CAP129 - Communicate Quality Measure Data	Support Multi-Patient Stored Query to return multiple documents for stored Query	General	Asserted to enable quality data retrieval support to enable pull of repository data
IS06-C[407]	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/CAP129 - Communicate Quality Measure Data	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



Number	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
IS06-C[408]	Query filters	HITSP/CAP129 - Communicate Quality Measure Data 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

Table 3-8 Additional Constraints on XDS Metadata Elements

XDS Metadata Attribute	Optionality	Extended Discussion	Source Type
XDSDocumentEntry.eventCodeList	O	See 3.2.3.1	CADT
XDSDocumentEntry.confidentialityCode	R	See 3.2.3.2	FAD
XDSDocumentEntry.patientID and XDSSubmissionSet.patientID	R	See 3.2.3.3	SAT
XDSDocumentEntry.sourcePatientID and XDSSubmissionSet.sourcePatientID	R	See 3.2.3.4	SAT

3.2.3.1 XDSDOCUMENTENTRY.EVENTCODELIST

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

3.2.3.2 XDSDOCUMENTENTRY.CONFIDENTIALITYCODE

The confidentialityCode attribute shall contain the following OID when the submitted document has been pseudonymized according to HITSP/CAP138 Retrieve Pseudonym:
2.16.840.1.113883.3.88.5.2.1.

3.2.3.3 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/CAP138 Retrieve Pseudonym.

3.2.3.4 XDSDOCUMENTENTRY.SOURCEPATIENTID AND XDSSUBMISSIONSET.SOURCEPATIENTID

The XDSDocumentEntry.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/CAP138 Retrieve Pseudonym.



4.0 CAPABILITY GAPS

Section 4.0 identifies gaps not met by existing Capabilities but needed to achieve the aims of the Harmonization Request for which this Interoperability Specification is written. This includes overlaps in Capabilities as well. The following table details how this section of the document is targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 4-1 Reader's Guide for Section 4.0

Document Section	Section Number	Intended Audience	Information Contained
Section 4.0	4.0	Business Analysts Development Team Architects	Gaps specific to Capabilities used as part of this Interoperability Specification are reviewed in this section to determine why specific information exchange requirements may not yet be met or defined. Readers should check this section to track the progress of gap resolution

The following table identifies gaps not met by or overlapping with existing Capabilities as described above.

Table 4-2 Capability Gaps

IER Gap Description	Responsible HITSP TC	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Standard value sets to represent allergies, intolerances, and adverse reactions is required. Additionally, a method to represent severity of such allergies, intolerances and adverse reactions is required. The value set taxonomy can potentially be used to represent severity (e.g., value sets for - severe life-threatening allergy, mild allergic reaction, etc.)	Population Perspective TC	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	Terminology	ISO, IHTSDO, WHO - Conceptual Framework for International Classification for Patient Safety	Pending SDO evaluation



IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: History-clinical trial enrollment and type of clinical trial is difficult to capture at the appropriate level of precision in ICD9-CM 'v' codes and in SNOMED-CT	Population Perspective TC, CMHR	Refer gap resolution to NCVHS	Terminology, Specification	Need referral to HL7, IHTSDO	Pending SDO evaluation
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: 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: HL7 O13. The EHR would typically receive an NCPDP fulfillment and store it in the EHR. All EHRs do not currently store such dispensing information in their medication lists. This is currently a workflow/implementation gap in many environments for processing	Population Perspective TC	Refer to Certification Organizations, e.g., CCHIT, to include certification requirements for dispensing information within EHR medication lists; include a requirement for inclusion of such information in EHR implementation requirements and potentially future measures of effective EHR usage	Specification	Certification Organizations, e.g., CCHIT, to include certification requirements for dispensing information within EHR medication lists; include a requirement for inclusion of such information in EHR implementation requirements and potentially future measures of effective EHR usage	Pending Certification organization process
IS06-IER10 Send Patient-Level Quality Data: Procedure-inpatient (end/closure) - Some measures require the start and the end time of individual procedures. The start time of operating room procedures can be identified on the anesthesia record, but no standard for interoperable transmission of that record is yet available. Similarly, the procedure end time is not clearly defined nor is one available. The requirement is also to determine which element to use to specify the end of the procedure. Potentially derived element from procedure start time and procedure minutes (HL7)	Population Perspective TC	HL7 Referral. A standard method to capture and interoperably transmit procedure-related start and end times (as well as additional information about the procedure) is required. This will be input to Structured Measure Definitions	HL7	January 2010 ballot: HL7 Implementation Guide for Clinical Document Architecture, Release 2: Procedure Note, Release 1 (1st DSTU Ballot)	2010



IS06-IER14 Send Patient-Level Aggregate Measure Report: Missing standard for communicate reporting of aggregate performance with respect to quality measures (i.e., all patients who meet denominator criteria)	Population Perspective TC	Work with HL7 to complete QRDA level 2 (all patients who meet denominator criteria) and 3 (summary reporting)	Specification	HL7 (Standard on hold)	Pending SDO evaluation
IS06-IER3, IS06-IER4, IS06-IER5, IS06-IER10, IS06-IER-11, IS06-IER-13, IS06-IER-19, IS06-IER-20 Send Patient-Level Quality Data: Concepts missing to support measure requirements (e.g., Education) Publish/Register Patient-Level Quality Data A standard methodology is required for managing content with respect to education/communication with patients and with other providers. Resolution requires some information modeling standardization and some terminology enhancements	Population Perspective TC	Work with HL7 to evaluate with respect to the RIM and CDA modules, and SNOMED-CT to model education/communication with patients and with other providers. Work with SNOMED-CT to add concepts needed for Quality and establish an ongoing approach; need a consistent approach that supports the measures	Information Modeling and Terminology	HL7 IHTSDO	Pending SDO evaluation
IS06-IER1 Send Measure Specification, IS06-IER10 Send Patient-Level Quality Data: There is no standard method to handle post-coordination of concepts (e.g., with SNOMED concepts). As an example, severity for systolic dysfunction requires the post-coordination of two concepts, 'severe' and 'systolic dysfunction'. Alternatively, pre-coordinated terms are available. A consistent approach to post-coordination is preferred	Population Perspective TC	Need SDO and IHTSDO Evaluation to recommend a standard methodology for post-coordination that can be implemented consistently among electronic vendor products. Similarly require certification entities (e.g., CCHIT) to require such standard methodology as part of certification criteria and for implementation guidance. Refer to list of measures provided for concepts required; For those not in SNOMED, request that they be added	Implementation Guides	IHTSDO HL7 CCHIT	Pending SDO evaluation



IS06-IER1 Send Measure Specification, IS06-IER11 Send Patient-Level Quality Data: ICNP is not in SNOMED CT International Classification of Nursing Practice (ICNP) provides a framework for coordination of care as well as nursing terminology. The framework is not consistent with SNOMED CT	Population Perspective TC	Recommend that ICNP and IHTSDO work together to harmonize	Terminology	ICNP, IHTSDO	Pending SDO evaluation
IS06-IER1 Send Measure Specification, IS06-IER10 Send Patient-Level Quality Data: 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	Population Perspective TC	This will be a matter of training. If there is a demographic resource (e.g., IHE-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	NA	NA	NA



Consult is an example of a procedure order, IS06-IER5 Request & Response Patient-Level Quality Data: 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. Gap for electronic capture of "consult ordered"; there are many ways to determine this information, but no good standard identified. Example: Consult report with appropriate components (e.g., an eye exam with appropriate components documented), (b) appropriate procedure code performed by a specialist (e.g., dilated eye examination coded with ICD-9 procedure code, or CPT procedure code) can help, but may not be sufficient. To accomplish this end, a standard specialty evaluation note/document will be helpful. Need to manage the status of all referrals and orders	Population Perspective TC	Referred to CMHR for resolution of Lab ordering (in progress) as well as procedure ordering. Encourage development of standard consultation/specialty evaluation note (e.g., a CDA template) to enable determination of consult completed. For consult ordered, referral order to an appropriate value set of acceptable roles will be helpful, but requires a clear definition of available roles from which a value set can be developed. Explore incorporation of communication transaction notification	terminology, Specification	LOINC/Ongoing work in CMHR Pending Referral: HL7, IHTSDO	Lab Orders January 2010; Procedure orders pending SDO Review
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Value set format not specified	Population Perspective TC	Work with HL7 to finalize MIF or identify other SDO with appropriate standard format for Value Sets	Specification	HL7	Pending SDO evaluation



<p>IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: History-clinical trial enrollment trial and type of clinical trial is difficult to capture at the appropriate level of precision in ICD9-CM 'v' codes and in SNOMED-CT. Need a set of elements for clinical research that address phases. Also need to capture:</p> <ul style="list-style-type: none"> · 'Reason for the Study'. · Clinical Trial Identifier · Inclusion/Exclusion Criteria <p>Consent for Treatment</p> <ul style="list-style-type: none"> · event criteria (CONS, event criteria) · Clinical Trial Participant · Patient ID linked with multiple phases of clinical trials 	<p>Population Perspective TC, CMHR</p>	<p>HITSP needs to provide modeling for consistent representation of Clinical Trial Enrollment. Pending CMHR work to add a new module for clinical trials to data dictionary.</p> <p>Trial registries – interfaces not necessarily standardized interface e.g. Clinical trial.gov</p> <p>Grants that relate to clinical research such as a lifestyle change could be counted as a trial that requires exclusion</p> <p>Existing measure needing this can leverage SNOMED Concept 'patient entered into trial', NOTE: Need Clinical trial identifier – included any research study</p> <p>NOTE: Reason for the study is needed</p> <p>NOTE: Need to be able to link the Patient ID with the multiple phases of the clinical trials</p> <p>NOTE: Need to link up with different types of trials that may not be medication-focused</p> <p>NOTE: Need a set of elements for clinical research that address phases</p> <p>NOTE: Trial registries – interfaces not necessarily standardized interface e.g. Clinical trial.gov</p> <p>Consider: Grants that relate to clinical research such as a lifestyle change could be counted as a trial that requires exclusion</p> <p>Consider: Within clinical document – observation that they are in a clinical trial; reason for trial may be a broad reason e.g. VTE, IRB</p> <p>Review: SNOMED Concept 'patient entered into trial'</p> <p>Consider Relationship: Consent for treatment (clinical trial)</p>	<p>Terminology, Specification</p>	<p>Pending Referral to HL7, IHTSDO</p>	<p>Pending SDO evaluation</p>
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IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Risk category/assessment Need to look at modeling and possibly additional attributes associated with risk Need to identify standard vocabulary and model Risk Not in C83 today– Risk mood is not supported in CDA CDS support where there is additional data in forms (e.g. Braden scale, APACHE scores – may be separate documents) Each assessment needs to be reviewed; HITSP needs a Capability to use the forms that will change over time; The result of such scales is identifiable as a clinical finding currently in HL7	Population Perspective TC	Assessments – ongoing work: observations and Short-term: scores in studies and results section for e.g. Braden score assessment ; clinical LOINC to specify risk category; IHE assessments Clinical procedure assessment use LOINC; for Result of procedure – SNOMED Code Range may be associated with clinical interpretation which may be SNOMED; has Scale e.g. risk for xx with value Collecting data – standardizing, may need a separate CDA type document	Specification, Terminology	HL7, IHE	Pending SDO evaluation
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Patient care experience · no direct EHR modeling available - not an EHR issue · MAY be captured through a survey tool · Objective measurement based on EHR-derived data; will use other data types such as encounter/PHR types; direct information from patients may come from survey data May be determined from various times of services/care provision	Population Perspective TC, Admin/Finance Domain TC	Refer to clinical LOINC Review specification options for patient survey instrument with HITSP Admin/Finance Identify an SDO for further development of information models for Patient Care Experience	Specification, Terminology	LOINC, IHTSDO, Other SDO TBD	Pending further examples of need
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Provider care experience e.g.: structural measure on how long it takes to enter problem list data; Not an EHR issue	Population Perspective TC, Admin/Finance Domain TC	Refer to clinical LOINC Identify an SDO for further development of information models for Provider Care Experience	Specification, Terminology	LOINC, IHTSDO, Other SDO TBD	Pending further examples of need



IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Patient survey not information that is specifically within an EHR	Population Perspective TC, Admin/Finance Domain TC	Admin and Finance Topic Identify an SDO for further development of information models for Patient Survey	Specification, Terminology	LOINC, IHTSDO, Other SDO TBD	Pending further examples of need
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Provider survey not information that is specifically within an EHR	Population Perspective TC, Admin/Finance Domain TC	Admin and Finance Topic Identify an SDO for further development of information models for Provider Survey	Specification, Terminology	LOINC, IHTSDO, Other SDO TBD	Pending further examples of need
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: System characteristic CDA facility modeling exists for SOME high-level attributes, but much of this information may be May be in HR system or other non-EHR system Attributes: Availability of resources <ul style="list-style-type: none"> • DME • Meds on-hand • Availability of resources in community • Number of beds • Nurse/staff ratios • State regulation/ability to receive an e-prescription • Service Agreements • System unavailable • Expand on Facility Attributes NOTE: Existing SNOMED Codes exist for: Supplied not available, off market, treatment Findings	Population Perspective TC, CMHR Domain TC, Admin/Finance Domain TC	Review modeling with CMHR and Admin/Finance within HITSP to further assess Gap resolution	Specification, Terminology	HL7	Pending SDO evaluation
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Functional status	Population Perspective TC, CMHR Domain TC	(Work in Progress): Future HITSP work (harmonization in progress with HL7 in the area of assessments). Public comment Anticipated Feb 2010 Review Risk Category Assessment modeling; Consider Constraining with IHE FSA templates Vocabulary may be supported by be clinical LOINC, SNOMED, ICD9/10, HL7 demographic codes	Specification	HL7	2010
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Functional status survey	Population Perspective TC, CMHR Domain TC	Pending HITSP work - LTC Extension (Wave 2) Align with Cap 119 update for September 2009; Clinical notes	HITSP Specification	HITSP CMHR	LTC Extension



IS06-IER10 Send Patient-Level Quality Data, , IS06-IER11 Publish/Register Patient-Level Quality Data: Substance administered no way to easily represent : non-medication administration (e.g. Oxygen administered by respiratory tpy, food - assessment whether can be given food) SNOMED Situation with Context can express the administration of oxygen (and other substances)	Population Perspective TC, CMHR Domain TC	Modeling required	Specification, Terminology	HL7, IHTSDO	Pending SDO evaluation
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Substance ordered	Population Perspective TC, CMHR Domain TC	Modeling Work Need to be able to link the constructs of the action with the specifics of what was ordered	Specification	HL7	Pending SDO evaluation
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Care goal no coded section in Plan of Care	Population Perspective TC, CMHR Domain TC	Pending HITSP CMHR Data Dictionary and Modeling	Specification	IHE	2010
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Care Plan	Population Perspective TC, CMHR Domain TC	Work Pending (Tier 2): NOTE: See IHE PPOC	Specification	IHE	2010
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Communication provider to provider; Not documentation necessarily managed within the EHR – look to logs; Need to be able to deal with any communication. This needs to also address ambulatory and all other encounter settings (e.g. telephone communication, electronic communication); No clinical audit standard currently available to support capturing this information from the logs	Population Perspective TC	An EHR utilization element, not a clinical element; Refer to HITSP activities in Infrastructure and operations; Monitor HL7 Consultation notes (constraint on CDA); Follow new work activities from ISO TC215 WG4	Specification	ISO TC215, HL7	New Work Item Proposal pending



IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Medication Order: Days Supplied. Outpatient duration – not available in wide enough implementation to expect this will be sufficient	Population Perspective TC, Admin/Finance Domain TC	Certification requirements needed to be sure these are implemented in EHRs	Specification	Certification Organizations, e.g., CCHIT	NA
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Device applied. Current HITSP work was for the simple Personal Health Device; Within the PCF framework there is a messaging framework	Population Perspective TC	All interventions should be determined clinically and documented in the EHR. There is no clear standard to handle documentation that interventions have occurred that do not require a procedure note. Monitor Work in SDO · map from data model in the devices world to the RIM, to the CDA HL7 Gas WG (anesthesia) – around a CDA for an Anesthesia record. Capture of waveform streams – HL7 project ongoing	Specification	HL7	2010
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Device order - summary of the fact that a device was ordered during the stay needs to be available in the CDA. Dependency on the identifier/vocabulary for the device to be ordered	Population Perspective TC	HITSP CMHR modeling pending overlap resolution for identifier vocabulary	Terminology	ISO TC215, HL7	2010
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Device Applied; No ability to reference the device as an identifier associated with surgical procedure	Population Perspective TC	Monitor ongoing standardization to harmonize vocabularies for identification of devices	Terminology	ISO TC215, HL7	2010
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Device allergy or adverse reaction. Currently cannot identify device as source of allergy, only as consumable – placing participant as a consumable will require future harmonization	Population Perspective TC, CMHR Domain TC	Will require discussion with Structured Documents Committee to identify the gap. Need to label as a participation type of device (HL7 V.3), not a consumable. Participation types (e.g. causative agent, factor, chemical substance, reagent, microorganisms). In CCD, agent is represented as causative agents, will need to manage errata for CCD through the HL7 process. Monitor SDO Activity: HL7 activity for applying adverse event reporting to devices; JIC possible	Specification	ISO TC215, HL7	Pending SDO Evaluation



<p>IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Declined (medication, device, procedure, substance, etc); The ActReason codes do not support a hierarchy that would classify the types of reasons in a manner to support quality exclusions: Patient Reason, Medical Reason and System Reason;</p> <p>Need a terminology, taxonomy, and definition for exclusions</p> <p>Require a terminology, taxonomy, and definition for contraindications or exclusions that cannot be specified by existing HITEP quality data types. These exclusions specifically have three categories: medical reason (clinician-determined patient contraindication not specified elsewhere in the measure), patient reason (patient-determined contraindication not specified elsewhere in the measure), and system reason (lack of specific resources that are out of control of the provider - e.g., medication recall causing regional or national shortage)</p>	<p>Population Perspective TC</p>	<p>Refer to SDOs - HL7 has a concept for ActReason negation that requires additional specification - i.e., create a hierarchy of medical reason, patient reason, system reason. Additional input from IHTSDO is required to determine if SNOMED concepts are sufficient to fill these slots in HL7 messaging.</p> <p>The solution will require approaching HL7 to establish the allowable reasons as a hierarchy of terms. Proposed grouping based on current HL7 actReason:</p> <p>PATIENT REASON</p> <p>21491 _ControlActReason</p> <ul style="list-style-type: none"> - 21701_MedicationOrderAbortReasonCode <ul style="list-style-type: none"> o 21710 patient refuse o 21708 unable to use - 22849_PharmacySupplyEventAbortReason <ul style="list-style-type: none"> o 22851 patient changed mind <p>MEDICAL REASON</p> <p>21491 _ControlActReason</p> <ul style="list-style-type: none"> - 21701_MedicationOrderAbortReasonCode - 21703 ineffective - 21704 no longer required for Tx - 22849_PharmacySupplyEventAbortReason - 22855 contraindication - 21737_SupplyOrderAbortReasonCode - 21990 intolerance - 21738 new therapy <p>SYSTEM REASON</p> <p>21408_ReasonForNotEvaluatingDevice</p> <p>22164_ActCoverageReason (Act Coverage Reason) derived:</p> <ul style="list-style-type: none"> - 22168_ActCoverageProviderReason - 22169_ActCoverageServiceReason - 22165_CoverageExclusionReason - 22166_CoverageFinancialParticipationReason - 22167_CoverageLimitationReason - 21493_EligibilityActReasonCode) <p>20940._ActIneligibilityReason -- derived:</p> <ul style="list-style-type: none"> - 19731 coverage suspended - 19730 registered in error <p>20941_ActInvoiceCancelReason</p> <ul style="list-style-type: none"> - 19733 incorrect covered party as patient - 19735 incorrect billing - 19734 incorrect policy - 19736 incorrect provider <p>22809_ControlActNullificationReasonCode</p> <ul style="list-style-type: none"> - 22024 altered decision - 22023 entered in error 	<p>Terminology</p>	<p>HL-7, IHTSDO Referral pending for some vocabulary. ISO TC215 evaluating new quality work</p>	<p>Pending SDO evaluation</p>
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IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Physical Findings GAP - Need to identify "source" of physical exam finding (e.g. a device originated value, patient originated, clinician taken)	Population Perspective TC	Coordinate with CMHR ...or SDO GAP	Specification, Terminology	HL7	Pending SDO evaluation
IS06-IER10 Send Patient-Level Quality Data, IS06-IER11 Publish/Register Patient-Level Quality Data: Dietetics and Nutrition focused attributes and terminologies	Population Perspective TC, CMHR Domain TC	Deferred. Pending further analysis of requirements for information and standards in this area	Terminology	IHTSDO	Pending further analysis of requirements for information and standards in this area

4.1 STANDARD OVERLAPS

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

Table 4-3 Harmonization Request Requirements and Associated Standard Overlaps

Requirement Number	Summary Description	Standard Overlap	Recommended Resolution
IS06-IER10, IS06-IER11	Send Patient-Level Quality Data Publish/Register Patient-Level Quality Data	(Device, Medication, Procedure, Substance) Declined: there are alternative solutions – 1) consistent with ActMood and reason codes 2) one that uses SNOMED codes; the information model is not clear for this option . The use of SNOMED with the ActReason maynot be consistent with TermInfo requirements in HL7. • HL7 ActMood = INT negation IND = True has Reason where HL7 ActReason -- 3 categories	To be considered is a hybrid solution in which the Act can be defined as a SNOMED term and the model to represent the use is based on the ActMood=INT negation IND=True has Reason; using the HL7 allowable terms as reasons. The solution will require approaching HL7 to modify the allowable reasons to SNOMED terms
IS06-IER4	Pre-populate form Patient-Level Quality Data	UN Standard product and services code – Coalition for healthcare e-standards; overlaps with LOINC possible	Pending further review
IS06-IER10, IS06-IER11	Send Patient-Level Quality Data Publish/Register Patient-Level Quality Data	Procedure performed: provider role Vocabulary for Provider Role Role term is used in various standards differently	Need clarification from HITEP regarding provider-patient relationship (e.g., attending, admitting, PCP, consultant) required for attribution. Pending CMHR Modeling once further attribution requirements are identified
IS06-IER10, IS06-IER11	Send Patient-Level Quality Data Publish/Register Patient-Level Quality Data	Procedure performed: Procedure Code	Vocabulary selection – harmonization is needed



Requirement Number	Summary Description	Standard Overlap	Recommended Resolution
IS06-IER10, IS06-IER11	Send Patient-Level Quality Data Publish/Register Patient-Level Quality Data	Device applied No national or international consensus for which identifier system to use – no uniform way to identify an identifier for the device as an instance of the device. Unique device instance IDs (EUI 64) <ul style="list-style-type: none"> Nationally - UMDNS vs Universal Medical Device Nomenclature System owned by UCRI GMDN – Global medical device nomenclature – moving target – ongoing SDO activities working with GS1 (Global Harmonization Task Force – GHTF) HCPCS 	Pending HITSP Tier 2 Awaiting Unique device identification guidance due from FDA sometime this year
IS06-IER10, IS06-IER11	Send Patient-Level Quality Data Publish/Register Patient-Level Quality Data	Device Identifier No national or international consensus for which identifier system to use – no uniform way to identify an identifier for the device as an instance of the device. Unique device instance IDs (EUI 64) <ul style="list-style-type: none"> Nationally - UMDNS vs Universal Medical Device Nomenclature System owned by UCRI GMDN – Global medical device nomenclature – moving target – ongoing SDO activities working with GS1 (Global Harmonization Task Force – GHTF) SPL Structure Product Labeling HCPCS 	Pending HITSP Tier 2 Awaiting Unique device identification guidance due from FDA sometime this year
IS06-IER10, IS06-IER11	Send Patient-Level Quality Data Publish/Register Patient-Level Quality Data	Device Serial Number No national or international consensus for which identifier system to use – no uniform way to identify an identifier for the device as an instance of the device. Unique device instance IDs (EUI 64) <ul style="list-style-type: none"> Nationally - UMDNS vs Universal Medical Device Nomenclature System owned by UCRI GMDN – Global medical device nomenclature – moving target – ongoing SDO activities working with GS1 (Global Harmonization Task Force – GHTF) SPL Structure Product Labeling HCPCS 	Pending HITSP Tier 2 Awaiting Unique device identification guidance due from FDA sometime this year
IS06-IER10, IS06-IER11	Send Patient-Level Quality Data Publish/Register Patient-Level Quality Data	Manufacturer No national or international consensus for which identifier system to use – no uniform way to identify an identifier for the device as an instance of the device. Unique device instance IDs (EUI 64) <ul style="list-style-type: none"> Nationally - UMDNS vs Universal Medical Device Nomenclature System owned by UCRI GMDN – Global medical device nomenclature – moving target – ongoing SDO activities working with GS1 (Global Harmonization Task Force – GHTF) SPL Structure Product Labeling HCPCS 	Pending HITSP Tier 2 Awaiting Unique device identification guidance due from FDA sometime this year



Requirement Number	Summary Description	Standard Overlap	Recommended Resolution
IS06-IER10, IS06-IER11	Send Patient-Level Quality Data Publish/Register Patient-Level Quality Data	Risk Category Assessment Model and Vocabulary selection Risk mood is not supported in CDA	CMHR Pending work to review modeling and possibly additional attributes associated with risk. Monitor ongoing work in clinical LOINC to specify risk category Interim Recommendation: Clinical procedure assessment use LOINC; for Result of procedure – SNOMED Code NOTE: Range may be associated with clinical interpretation which may be SNOMED; has Scale e.g. risk for xx with value



5.0 APPENDIX

The following sections include relevant materials referenced throughout this document. The following table details how this section of the document is targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 5-1 Reader's Guide for Section 5.0

Document Section	Section Number	Intended Audience	Information Contained
Section 5.0	5.1 Provisional Exchange Content Description	Architects	Supporting information is provided for HITSP exchange content that is identified as provisional (due to gaps identified in the previous section)
	5.2 Provisional Data Requirements	Architects	Supporting information is provided for HITSP data requirements that are associated with provisional exchange content identified in Section 5.1
	5.3 Harmonization Request Traceability	Architects Business Analysts	A complete mapping of information exchange requirements to functional requirements is provided in this section. Readers can trace IER's to underlying Harmonization Request events and actions (in those instances where a Use Case exists) or to functional requirements defined as part of an official standards Harmonization Request

5.1 PROVISIONAL EXCHANGE CONTENT DESCRIPTIONS

The exchange content descriptions answer one or more data requirements, and map to existing or planned HITSP constructs. In this section, any provisional exchange content descriptions identified for IERs that address gaps are described

Table 5-2 New Exchange Content Data Requirements

Exchange Content Number	Exchange Content Name	Exchange Content Definition	Data Requirements	Qualifier
EC 28	Emergency Encounter Summary	Data from multiple sources (such as physicians, nurses, technologists, etc.) Recording the assessments and care delivered by the ED team in response to an ED visit. It is a summary of the patient's current health status and care tendered in the ED between arrival and ED departure. Includes triage note, nursing note, composite triage and nursing note, and ED physician note	<ul style="list-style-type: none">• PDR50 - Fully Coded Lab Results• PDR 67 - ED Triage Note• ED Nursing Note• Composite ED Triage and ED Nursing Note• ED Physician Note• Pre-hospital Care Report• EDR (Emergency Department Referral)• Diagnostic Imaging Reports• Consultations – future document type specification• Transfer Summary – future document type specification• Summary of Death – future document type specification	



Exchange Content Number	Exchange Content Name	Exchange Content Definition	Data Requirements	Qualifier
EC 48	Encounter Summary	Document-based patient encounter data (excluding laboratory, radiology)	<ul style="list-style-type: none"> • DR31 Problem List • DR01 Admission Medications History • DR15 Hospital Admission Diagnosis • DR02 Advance Directives • DR03 Allergies and Other Adverse Reactions • DR08 Discharge Diagnosis • DR38 Discharge Diet • DR17 Hospital Discharge Medications • DR07 Diagnostic Results • DR11 Functional Status • DR14 History of Present Illness • DR16 Hospital Course • DR22 Medical Equipment • DR27 Personal Information • DR28 Physical Examination • DR29 Plan of Care • DR13 History of Past Illness • DR34 Review of Systems • DR24 Medications Administered • DR37 Vital Signs 	
EC 32	Summary of Care	Describes the document content summarizing a consumer's registration, medication and health data information	<ul style="list-style-type: none"> • DR02 Advance Directives • DR03 Allergies and Other Adverse Reactions • DR06 Comment • DR31 Problem List • DR09 Encounters • DR12 Healthcare Providers • DR18 Immunizations • DR19 Information Source • DR26 Payers • DR20 Language Spoken • DR23 Medications • DR27 Personal Information • DR29 Plan of Care • DR30 Pregnancy • DR32 Procedure • DR36 Support • DR37 Vital Signs 	
EC 105	Patient-Level Quality Data	Defines the data to support the communication of patient level quality data for quality measurement	<ul style="list-style-type: none"> • DR02 Advance Directives • DR03 Allergies and Other Adverse Reactions • DR08 Discharge Diagnosis • DR23 Medications • DR24 Medications Administered • DR25 Orders • DR27 Personal Information • DR29 Plan of Care • DR31 Problem List • DR32 Procedure • DR37 Vital Signs • Encounter • Result • Study Findings (diagnostic/radiology) • Discharge Instructions • Consultation Notes 	Data requirements are based upon HITEP and will be updated to HITEP II specifications. Detailed data requirements are specified in HITSP/C105



Exchange Content Number	Exchange Content Name	Exchange Content Definition	Data Requirements	Qualifier
EC 106	Measure Specification	A structured document that enables electronic communication and processing of quality measurement criteria	Quality Measurement data, including (but not limited to): <ul style="list-style-type: none"> • Measure is expressed in a structured, codified format • Measure may be communicated through point-to-point (XML possibly) or document sharing (CDA possibly) • A human readable translation is required • Data integrity check • Vocabulary constraints (system, version, number, text) for measure numerator/denominator sections • Metadata • Measure ID • Measure name • Measure description (including definition of terms) • Instructions on reporting including frequency, timeframes, and applicability • Topic type • Measure developer • Date sent • Version • Approved by • Date of original approval • Adoption by regulatory bodies and programs used by the regulatory bodies • Rationale (includes Clinical area) • Improvement notation (expected outcome includes clinical area) • Version changes • Measurement start date • Measurement end date • Contact (not in the collaborative import data) • Date of version (effective date of the version not in the collaborative import data) • Level of analysis (who should adopt this) • Measure Report 	

5.2 PROVISIONAL DATA REQUIREMENTS

In this section, any provisional data requirement descriptions identified for provisional exchange contents listed above are described.

5.3 HARMONIZATION REQUEST TRACEABILITY

This section describes the traceability to the Harmonization Request for which this IS is written. The Traceability may be described in terms of events and actions, or in terms of functional requirements.

This table relates the events of a Harmonization Request to the actions taken and information exchanges required.



Table 5-3 Harmonization Request Events and Actions Analysis Table

Event	Action	Information Exchange Requirement(s) (includes security requirements)
6.1.1, 7.1.1 Receive listing of defined measures & abstraction guidelines.	6.1.1.1 Hospitals receive the listing of quality measures and detailed measure specifications for how a quality measure will be calculated 7.1.1.1 Clinicians receive the listing of quality measures and detailed measure specifications for how a quality measure will be calculated	IS06-IER1 Send Measure Specification
	6.1.1.2 Hospitals identify applicable measures and incorporate into EHR where possible 7.1.1.2 Clinician organizations identify the measures which apply to their patient population	IS06-IER2 Request & Response Value Sets
		IS06-IER5 Request & Response Measure Specification
6.1.2, 7.1.2 Perform and document patient care	6.1.2.1, 7.1.2.1 Clinical personnel treat the patient's injuries or illness. The patient is assessed and observations are documented; appropriate diagnostics and treatments are ordered and completed. Clinical information is entered into the patient's EHR	None
6.1.3, 7.1.3 Filter EHR data for information matching inclusion/exclusion factors	6.1.3.1, 7.1.3.1 Based on the defined measure specifications and associated technical specifications incorporated into the EHR workflow, the patients relevant for each "denominator" (a case relevant to include for a particular quality measure) are identified using information available. If the information is present, the patient is identified as eligible for the measure, based on inclusion criteria	IS06-IER2 Request & Response Value Sets
		IS06-IER3 Request Existing Patient Data Patient-Level Quality Data
	6.1.3.2, 7.1.3.2 Based on documentation entered by the clinician, the data are filtered by exclusion criteria for each case identified as eligible for a quality measure	IS06-IER2 Request & Response Value Sets
		IS06-IER3 Request Existing Patient Data Patient-Level Quality Data
		IS06-IER4 Pre-populate form Patient-Level Quality Data
		IS06-IER6 Request & Response Summary of Care
		IS06-IER7 Request & Response Encounter Summary
		IS06-IER8 Request & Response Emergency Encounter Summary
		IS06-IER9 Request & Response Consent Document
6.1.4 Discharge patient 7.1.4 Healthcare encounter ends	6.1.4.1 Once treatment is complete, the patient is discharged. Additional data may be extracted from the patient record to inform the quality measure. 7.1.4.1 The clinician concludes the healthcare encounter. Additional data may be extracted from the patient record to inform the quality measure	



Event	Action	Information Exchange Requirement(s) (includes security requirements)
6.1.5 Augment EHR data with manual extraction of patient data (may also occur prior to discharge.) 7.1.5 Merge claims data with EHR data and manual extraction of patient data	6.1.5.1 Information related to a quality measure that is not automated through an EHR is manually extracted from the patient record. 7.1.5.1 Claims data are merged with clinical information from an EHR. Information related to a quality measure that is not automated through an EHR is manually extracted from the patient record	IS06-IER4 Pre-populate Form for Patient-Level Quality Data
6.1.6, 7.1.6 Aggregate and validate patient information required for quality measures	6.1.6.1 Patient-level data matching the designated parameters required for the appropriate quality measure (including data automatically collected through the EHR, manually extracted data, and administrative data such as claims information), are retrieved and put into the specified format. 7.1.6.1 Clinician's personnel retrieve patient-level data matching the designated parameters required for the appropriate quality measure (including data automatically collected through claims data, the EHR, and manually extracted data), and prepare it in the specified format	IS06-IER2 Request & Response Value Sets
		IS06-IER3 Request Existing Patient Data Patient-Level Quality Data
		IS06-IER4 Pre-populate Form for Patient-Level Quality Data
		IS06-IER6 Request & Response Summary of Care
		IS06-IER7 Request & Response Encounter Summary
		IS06-IER8 Request & Response Emergency Encounter Summary
		IS06-IER9 Request & Response Consent Document
	6.1.6.2, 7.1.6.2 The hospital validates that the information aggregated is accurate	None
6.1.7, 7.1.7 Calculate quality measure, validate and correct if necessary	6.1.7.1 Based on the pre-defined measure specifications, quality measures are calculated using the patient-level data compiled	None
	6.1.7.2 An initial report with detailed, patient-level quality information and hospital-level quality measurement (including initial hospital scores per quality measure) is prepared either by the hospital or its support services. The patient-level information is validated by the hospital. Any corrections required are made and the measure is re-calculated. 7.1.7.2 An initial report with detailed, patient-level quality information and clinician-level quality measurement (including initial clinician scores per quality measure) is prepared. The patient-level information is validated by the clinician organization	IS06-IER2 Request & Response Value Sets
6.1.8, 7.1.8 Transmit patient-level quality information	6.1.8.1 Patient-level quality measures data are transmitted either by the hospital or by the hospital's support service to a Multi-hospital Measurement and Reporting entity. 7.1.8.1 Patient-level data are transmitted to a Multi-entity Measurement and Reporting entity	IS06-IER2 Request & Response Value Sets



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IS06-IER3 Request Existing Patient Data Patient-Level Quality Data
		IS06-IER4 Pre-populate Form for Patient-Level Quality Data
		IS06-IER6 Request & Response Summary of Care
		IS06-IER7 Request & Response Encounter Summary
		IS06-IER8 Request & Response Emergency Encounter Summary
		IS06-IER9 Request & Response Consent Document
		IS06-IER10 Send Patient-Level Quality Data
		IS06-IER11 Publish/Register Patient-Level Quality Data
		IS06-IER12 Publish/Register Consent Document
		IS06-IER13 Request & Response Patient-Level Quality Data
6.1.9 Receive and validate preview report of quality measures; provide corrections if required 7.1.9 Receive and validate preview report of quality measures; provide corrections if required	6.1.9.1 A preview report is received from the Multi-hospital Measurement and Reporting entity. The report is validated by the hospital for accuracy of the data 7.1.9.1 A preview report is received from Multi-entity Measurement and Reporting entity. The report is validated by the clinician organization for accuracy of the data	IS06-IER10 Send Patient-Level Quality Data
		IS06-IER13 Request & Response Patient-Level Quality Data
		IS06-IER14 Send Measure Report
	6.1.9.2 If data corrections are required, they are sent to the Multi-hospital Measurement and Reporting entity 7.1.9.2 If data corrections are required, they are sent to the Multi-entity Measurement and Reporting entity	IS06-IER10 Send Patient-Level Quality Data
		IS06-IER14 Send Measure Report
		IS06-IER13 Request & Response Patient-Level Quality Data
6.1.10, 7.1.10 Identify areas for improvement	6.1.10.1 Hospitals review quality data and use this information to guide internal quality improvement activities 7.1.10.1 Clinician organizations review quality data and use this information to guide internal quality improvement activities	None



Event	Action	Information Exchange Requirement(s) (includes security requirements)
6.1.11 Inform electronic work processes to prompt quality improvement at point of care and support efficient quality reporting. 7.1.11 Inform electronically supported clinical processes to prompt quality improvement at point of care and support efficient quality reporting	Action 6.1.11.1 Based upon analysis of quality measurement information (both initial report and preview report), electronic work processes may be modified to provide more relevant information for the treating clinician 7.1.11.1 Based upon analysis of quality measurement information (both initial report from internal measurement activities and preview report of public reporting activities), processes may be refined to provide more relevant information for the treating clinician	None
6.1.12, 7.1.12 Implement quality improvement initiatives	6.1.12.1 Clinicians modify practice based on feedback received 7.1.12.1 Clinicians modify practice based on feedback received	None
6.2.1, 7.2.1 Match patient-level longitudinal data.	6.2.1.1, 7.2.1.1 Patient-level information from multiple sources is matched to create a longitudinal view for a specific patient	IS06-IER15 Request & Response Patient Demographics
6.2.2, 7.2.2 As appropriate, pseudonymize or de-identify the patient-level data which are being readied for transmission. Pseudonymization allows for data to be re-linked if required by an authorized user	6.2.2.1, 7.2.2.1 A randomized data linker is provided to allow authorized entities the ability to re-link to the individual patient	IS06-IER16 Request & Response Pseudo-Identity
		IS06-IER10 Send Patient-Level Quality Data Anonymous data requirement
		IS06-IER11 Publish/Register Patient-Level Quality Data Anonymous data requirement
		IS06-IER13 Request & Response Patient-Level Quality Data
	6.2.2.2, 7.2.2.2 Required data are checked to ensure full compliance with privacy requirements	None
6.3.1, 7.1.3 Collect Information	6.3.1.1 Patient-level quality data as defined by quality measure specifications are received from the Hospital or from the hospital's vendor 7.3.1.1 Patient-level quality data as defined by measure specifications are received from the clinician or from contracted vendor	IS06-IER10 Send Patient-Level Quality Data
		IS06-IER13 Request & Response Patient-Level Quality Data
6.3.2 Calculate quality measures for each hospital 7.3.2 Calculate quality measures for each clinician	6.3.2.1 Based on the pre-defined measure specifications, hospital-level quality measures are calculated using the patient-level data submitted by hospitals. A preview report is prepared for each hospital 7.3.2.1 Based on the pre-defined measure specifications, clinician-level quality measures are calculated using the patient-level data submitted by clinicians. A preview report is prepared for each clinician	IS06-IER2 Request & Response Value Sets
		IS06-IER3 Request Existing Patient Data Patient-Level Quality Data



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IS06-IER4 Pre-populate Form for Patient-Level Quality Data
		IS06-IER6 Request & Response Summary of Care
		IS06-IER7 Request & Response Encounter Summary
		IS06-IER8 Request & Response Emergency Encounter Summary
		IS06-IER9 Request & Response Consent Document
		IS06-IER10 Send Patient-Level Quality Data
		IS06-IER13 Request & Response Patient-Level Quality Data
6.3.3 Transmit preview report of hospital-level quality measurement to validate/correct 7.3.3 Transmit preview report of clinician-level quality measurement to validate/correct	6.3.3.1 Preview reports of hospital-level quality measurement are sent to hospitals for data validation and if necessary, data correction, prior to reporting 7.3.3.1 Preview reports of hospital-level quality measurement are sent to clinicians for data validation and if necessary, data correction, prior to reporting	IS06-IER10 Send Patient-Level Quality Data
		IS06-IER14 Send Measure Report
		IS06-IER13 Request & Response Patient-Level Quality Data
6.3.4, 7.3.4 Re-calculate quality measures as needed	6.3.4.1 Revised quality information is received from the hospitals. The reports may be re-calculated again if necessary and sent to hospitals for data validation and correction if needed 6.3.4.1 Revised quality information is received from the clinicians. The reports may be re-calculated again if necessary and sent to clinicians for data validation and correction if needed	IS06-IER2 Request & Response Value Sets
		IS06-IER3 Request Existing Patient Data Patient-Level Quality Data
		IS06-IER4 Pre-populate Form for Patient-Level Quality Data
		IS06-IER6 Request & Response Summary of Care
		IS06-IER7 Request & Response Encounter Summary
		IS06-IER8 Request & Response Emergency Encounter Summary
		IS06-IER9 Request & Response Consent Document
		IS06-IER10 Send Patient-Level Quality Data
		IS06-IER13 Request & Response Patient-Level Quality Data



Event	Action	Information Exchange Requirement(s) (includes security requirements)
6.3.5, 7.3.5 Perform audit for accuracy of quality measurement	6.3.5.1 The Multi-hospital Measurement and Reporting entity conducts routine audits to ensure the integrity of the data submitted, and the accuracy of the quality measurement process 7.3.5.1 The Multi-entity Measurement and Reporting entity conducts routine audits of quality data	IS06-IER10 Send Patient-Level Quality Data Nonrepudiation of Origin requirement
		IS06-IER11 Publish/Register Patient-Level Quality Data Nonrepudiation of Origin requirement
		IS06-IER13 Request & Response Patient-Level Quality Data Nonrepudiation of Origin requirement
6.3.6, 7.3.6 Format and distribute quality information	6.3.6.1 The completed hospital-level quality measurement report is distributed and made available to users for viewing and possibly downloading 7.3.6.1 The completed clinician-level quality measurement report is distributed and made available to users for viewing and possibly downloading	IS06-IER14 Send Measure Report



6.0 DOCUMENT UPDATES

This section provides the history of changes made to this document.

6.1 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](#).

6.2 DECEMBER 13, 2007

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

6.3 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

6.4 AUGUST 27, 2008

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

6.5 JUNE 30, 2009

This document has been modified to reflect the updated HITSP approach documenting Interoperability Specifications in support of ARRA Tiger Teams. This document includes the following content updates:

- Replaced HITSP/C38 HITSP Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS) Component with new Component HITSP/C105 Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA) for communication of patient-level quality data
- Adds HITSP/T66 Retrieve Value Set
- Adds new Component HITSP/C106 Quality Measurement Criteria Component for communicating electronic measure specifications

Minor editorial changes were made to this document. Removed boilerplate text for simplification. The term “actor” was replaced with “interface”.

6.6 SEPTEMBER 30, 2009

The changes in this cycle address the following comments:

- 7165, 7281, 7283, 7422, 7423, 7425, 7426, 7427, 7428, 7430, 7431, 7432, 7433, 7434, 7435, 7436, 7437, 7438, 7439, 7440, 7441, 7442, 7443, 7444, 7483, 7484, 7485, 7486, 7487, 7488, 7489, 7490, 7491, 7492, 7493, 7494, 7495, 7496, 7497, 7498, 7499, 7520, 7521, 7522, 7523, 7524, 7525, 7526, 7527, 7528, 7529, 7530, 7531, 7532, 7533, 7534, 7535, 7536, 7169, 7184, 7225, 7226, 7244, 7300, 7302, 7230, 7231, 7237, 7213, 7214, 7281, 7283, 7156, 7170, 7171, 7172, 7173, 7174, 7175, 7176, 7177, 7178, 7179, 7180,



7181, 7182, 7183, 7211, 7212, 7220, 7221, 7222, 7223, 7224, 7229, 7232, 7234, 7235, 7239, 7240, 7241, 7243, 7303, 7165, 7209, 7227, 7228, 7215, 7216, 7217, 7219, 7238

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

6.7 NOVEMBER 9, 2009

- This document has been modified to match the updates to the template
- All appendix material was moved to HITSP/C154
- Removed all embedded Capabilities to reference external Capabilities and adjusted Constraint References to align with referenced Capabilities
- Unified Modeling Language (UML) diagrams were updated in Section 3.1 to show the Capabilities used between systems

6.8 JANUARY 18, 2010

- This document has been modified to match the HITSP Interoperability Specification Template Version 2.0
- The changes in this cycle address the following comments:
 - 8794, 8797, 8799, 8954, 8956, 8957, 8959, 8961, 8963, 8965, 8966, 8968

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

6.9 JANUARY 25, 2010

Upon approval by the HITSP Panel on January 25, 2010, this document is now Released for Implementation.

