Document Number: HITSP 09 N 427 Rev. 1

Date: September 15, 2009

HITSP

Healthcare Information Technology Standards Panel

Report from the Technical Committees & Tiger Teams

Arlington, VA | September 15, 2009

Presented by:

Joyce Sensmeier MS, RN-BC, CPHIMS, FHIMSS &

HITSP Technical Committee & Tiger Team Co-Chairs

Health Information Technology

Current Work Items 2009

Provider

General Lab Orders

Order Sets

Long Term Care Assessment

Admin/Finance

Scheduling

Prior-Authorization in Support of Treatment, Payment, & Operations

Consumer

Common Device Connectivity

Medical Home: Co-morbidity and Registries

Medication Gaps

Security/Privacy/ Infrastructure

Consumer Preferences
(shared with Consumer)

Common Data Transport

Population

Newborn Screening

Maternal/Child Health

Consumer Adverse Event Reporting

Quality Measures

Clinical Research

Care Management/ Health Records

Clinical Note Details

Data Architecture

Technical Committee Leadership

- **Population Perspective - 382 members**
  - Floyd P. Eisenberg, MD, MPH, National Quality Forum
  - Eileen Koski, M. Phil, Medco Health Solutions, Inc.
  - Anna Orlova, PhD, Public Health Data Standards Consortium
- **Consumer Perspective – 225 members**
  - Mureen Allen, MD, FACP, ActiveHealth Management
  - Charles Parisot, EHR Association
  - Scott Robertson, PharmD, Kaiser Permanente

Technical Committee Leadership

- **Provider Perspective – 269 members**
  - Allen Hobbs, PhD, Kaiser Permanente
  - Steve Hufnagel, PhD, DoD/Medical Health System (MHS)
  - Mike Lincoln, MD, Department of Veterans Affairs
- **Security, Privacy & Infrastructure Domain - 269 members**
  - Glen Marshall, Grok-A-Lot, LLC
  - John Moehrke, GE Healthcare
  - Walter Suarez, MD, Kaiser Permanente

Technical Committee Leadership

- **Care Management and Health Records Domain - 211 members**
  - Keith Boone, GE Healthcare
  - Corey Spears, McKesson Health Solutions
  - Greg Alexander, PhD, RN, Alliance for Nursing Informatics
- **Administrative and Financial Domain – 84 members**
  - Don Bechtel, Siemens Medical Solutions
  - Durwin Day, Health Care Service Corporation
  - Manick Rajendran, eZe Care LLC

Tiger Team Leadership

- **Clinical Research**
  - Walter Suarez, MD, Kaiser Permanente
- **Data Architecture**
  - Keith Boone, GE Healthcare
- **Quality Measures**
  - Floyd P. Eisenberg, MD, MPH, National Quality Forum
  - Eileen Koski, M. Phil, Medco Health Solutions, Inc.
- **Consumer Preferences**
  - Walter Suarez, MD, Kaiser Permanente
  - Mureen Allen, MD, FACP, ActiveHealth Management

Technical Committee/Tiger Team Membership – 850 individuals

Report from the Population Perspective Technical Committee

Newborn Screening Use Case - **Scenarios**

- *Ordering and Resulting:* This scenario covers initial screening both for Newborn Dried Blood Spot (NDBS) and Early Hearing Detection and Intervention (EHDI) and ends with the reporting of results, either within normal limits, or notification of the need for confirmatory testing if results are outside of normal limits.
- *Abnormal and Out of Range Results:* This scenario covers the processes in response to an out of range (or abnormal) screening test either from the NDBS or the EHDI.

Report from the Population Perspective Technical Committee

Newborn Screening Use Case - RDSS

Requirements & Design System Specification (RDSS) submitted to HITSP staff for technical & editorial review on September 14, 2009 in preparation for public comments (starting September 30, 2009)

Report from the Population Perspective Technical Committee

Newborn Screening Use Case - Systems

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	Electronic Health Record (EHR)/Personal Health Record (PHR) System Suppliers Clinicians, Healthcare Entities, Specialty Healthcare Entities
Health Information Exchange (HIE)	A Health Information Exchange (HIE) 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 Exchange Organizations
Public Health Information System	An automated and integrated system used to document and address information of interest to public health. Local, state, and federal government organizations and personnel use these systems to help protect and improve the health of their respective constituents. A critical effort under this charge is collecting health information to monitor for the existence of emerging health threats appearing in the population and manage these threats once manifested. Staff of these agencies interacts with the public health information system to verify and validate system indications of public health threats, and to assert acknowledgements that may be required by system processes	Government and Regulatory Agencies Knowledge Suppliers, Public Health Agencies Public Health Systems Suppliers, Registries Research Entities, Social Service Agencies
Laboratory Information Systems	Information system supporting the testing, analysis, and information management for laboratory organizations. Medical laboratories, in either in a hospital or ambulatory environment, which analyze specimens as ordered by clinicians to assess the health status of patients. Laboratories, depending on how they are affiliated with hospitals, can be part of either Individual Healthcare Facilities or Integrated Healthcare Data Suppliers. These business actors are responsible for updating interface engine rules and triggers in response to Use Case modifications of requested data feeds.	Laboratory Associations Laboratory Information System (LIS) Suppliers Testing Laboratories
Personal Health Record (PHR) Systems	A healthcare record system used to create, review, annotate and maintain records by the patient or the caregiver for a patient. The PHR may include any aspect(s) of the health condition, medications, medical problems, allergies, vaccination history, visit history or communications with healthcare providers	Personal Health Record (PHR) System Suppliers, Consumers, Patients
Hearing Screening System	A System used to measure and record the audiology function of the patient	Audiology Service Providers (Hearing Device Intermediary)

Report from the Population Perspective Technical Committee

Newborn Screening RDSS - Content

- Guidelines
- Consent to Procedure, Consent to Retain/Use Test Sample (store blood specimen for later use)
- Refusal of Screening, (EC 30 Consent Document Component (consent for sharing information)
- Education Brochures

Report from the Population Perspective Technical Committee

Newborn Screening RDSS – Content (continued)

Newborn Bloodspot Testing

- NBS Lab Order (Exchange Content (EC 23) Patient Demographics)
- NBS: pre-populate form from Birthing Summary (printing order on the specimen card)
- Birthing Summary
- Antepartum Summary
- Newborn Record
- Lab Result (used when constraint is ‘message’)
- Lab Result (used when constraint is ‘document’)
- Request for New Specimen (EC 23 Patient Demographics)
- Abnormal Results: Summary of Care, Referral Summary Discharge Summary Unstructured Data, Genetic Risk Decision Support

Report from the Population Perspective Technical Committee

Newborn Screening RDSS – Content (continued)

Hearing Screening

- Hearing Screening Order
- Hearing Screening Test Results
- Abnormal Results: Summary of Care, Referral Summary Discharge Summary Unstructured Data, Genetic Risk Decision Support

- EC 24 Pseudo-identity for public health surveillance purposes or protecting mother identity for adoption situations

Report from the Population Perspective Technical Committee

Newborn Screening RDSS - Capabilities

HITSP/CAP119 - Communicate Structured Document

HITSP/CAP120 - Communicate Unstructured Document

HITSP/CAP121 - Communicate Clinical Referral Request

HITSP/CAP122 - Retrieve Medical Knowledge

HITSP/CAP123 - Retrieve Existing Data

HITSP/CAP126 - Communicate Lab Results Message

HITSP/CAP127 - Communicate Lab Results Document

HITSP/CAP135 - Retrieve and Populate Form

HITSP/CAP136 - Communicate Emergency Alert

HITSP/CAP138 - Retrieve Pseudonym

HITSP/CAP142 - Retrieve Communications Recipient

HITSP/CAP143 - Manage Consumer Preference and Consents

Report from the Population Perspective Technical Committee

Newborn Screening RDSS – New Capabilities

- HITSP/CAP 99 - Communicate Laboratory Orders Message – *will work with Care Management TC & Provider Perspective TC*
- Communicate Procedure Orders – *will work with Care Management TC & Provider Perspective TC*
- Communicate Device Results Data – *will work with Provider Perspective TC*

Report from the Population Perspective Technical Committee

Newborn Screening RDSS – New HITSP Constructs

- Laboratory Order
- Hearing Screening Order
- Antepartum Summary
- Birthing Summaries
- Newborn Record
- Publish and Subscribe
- Consent to Procedure
- Consent to Retain Sample
- Consent Refusal
- Anonymize Newborn Screening Results

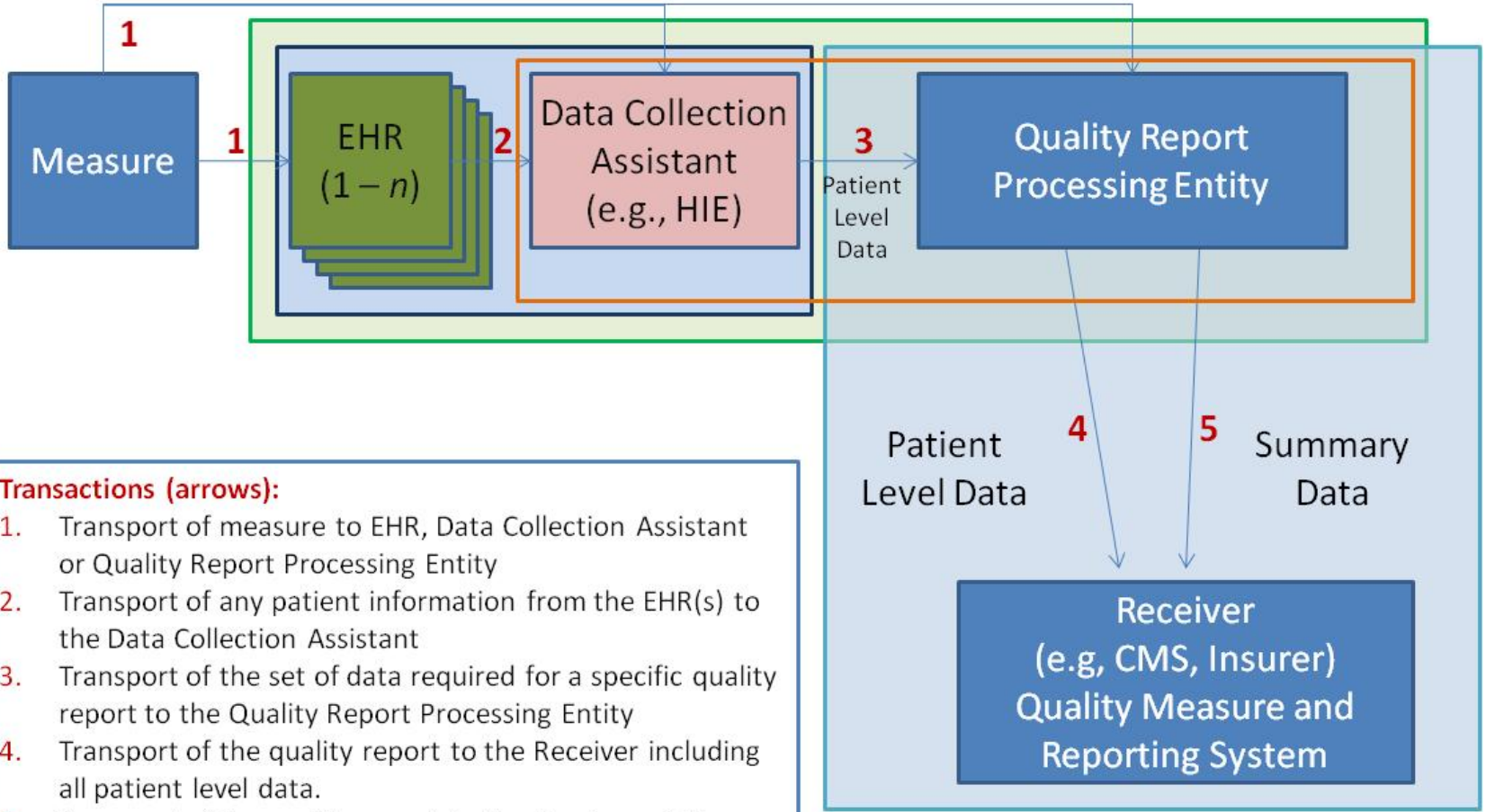
Report from the Population Perspective Technical Committee

Quality

- IS O6
- C105
- C106
- Measure recasting project

Report from the Population Perspective Technical Committee

Quality - IS O6 Clarification as to workflows related to CAP, SC



Transactions (arrows):

1. Transport of measure to EHR, Data Collection Assistant or Quality Report Processing Entity
2. Transport of any patient information from the EHR(s) to the Data Collection Assistant
3. Transport of the set of data required for a specific quality report to the Quality Report Processing Entity
4. Transport of the quality report to the Receiver including all patient level data.
5. Transport of the quality report to the Receiver of the performance summary.

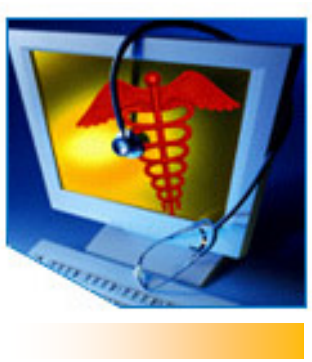
Report from the Population Perspective Technical Committee

Quality

- IS O6
  - Map HITEP II Data types to HITSP C154, C83, C80
  - Update template
- C105 – Patient level quality document using HL7 Quality Reporting Document Architecture (QRDA)
- C106 – Measurement criteria document – Provisional
  - **HL7 Version 3 Standard: Representation of the Health Quality Measures Format (eMeasure), Release 1 (V3_HQMF_R1_D1_2009SEP)**
- Measure recasting project
  - Value sets completed for all measures
  - Technical note completion date September 30
  - Testing plans in development for Connectathon, HIMSS Showcase

Document Number: HITSP 09 xxx

Date: September 15, 2009



HITSP

Healthcare Information Technology Standards Panel

Report from the Clinical Research Tiger Team

September 15, 2009

Presented by:

-- Walter G. Suarez, MD, MPH, Kaiser Permanente – TT Co-Chair

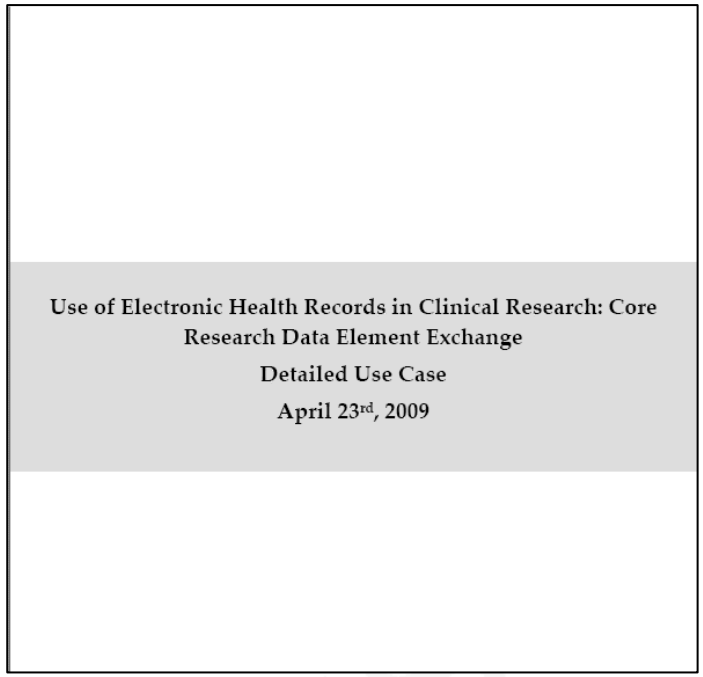
-- Gene Ginther, JBS International – Lead TT Facilitator

-- Landen Bain, CDISC – Lead TT Writer

HITSP
Clinical Research Tiger Team

Value Case

- Workgroup developed initial draft detailed value case and extensions (Nov 2008 – Feb 2009)
- Draft value case posted for public comment in March 2009
- Detailed value case completed by end of April, 2009; value case submitted HITSP for development of interoperability specifications
- Document describes three value scenarios:



Scenario Name	Scenario Description
Protocol-driven Sponsored Research	This scenario describes six processes that result in submission of clinical data to a sponsoring agency as dictated by a sponsor's protocol. It contains most of the data elements of interest
Registry Reporting	This scenario varies only slightly from the Sponsored Research Scenario, and describes the exchange of clinical data with a research registry or other related databases
Research Network	This third scenario, in which data originate in a networked environment, merely changes the mode of origination.

HITSP
Clinical Research Tiger Team

Status

- Tiger Team work started May 14, 2009
- Requirements Analysis completed July 28
  - Incorporates new HITSP Framework concepts of Capabilities and Service Collaborations
- Published RDSS for public comment July 31 through August 28
- Received 47 comments; completed review and successful resolution/disposition of comments September 3
- Refined the applicability of Service Collaborations to the value case

HITSP
Clinical Research Tiger Team

Status (cont.)

- Identified 14 data requirements, including study identifiers, subject demographics, family history, medical history, surgical history, medications history, physical examination, vital signs, diagnostic data, etc
- Identified 14 information exchange requirements, including: research network system sends patient header information to the electronic health data capture (EDC) system; EDC sends identifiers to research network system (RNS); EHR or RNS sends clinical research document (CRD) to EDC; EDC returns pre-populated Clinical Research Form (CRF) to EHR RNS
- Research protocol and confidentiality policy determines data elements to be included in each exchange

Table 5-3 Description of Information Exchange Requirements

Information Exchange Requirement Number (IER)	Description
IER1	Scenarios 1 and 3: EHR or research network system sends redacted patient header data (DR1, DR2, DR3, DR13) to EDC. Reference action 7.2.3.1. Confidentiality and consent policy configuration determines the specific data elements to be redacted.
IER2	Scenario 1 and 3: EDC sends pseudonymous subject identifier to research network system or site EHR. Reference action 7.3.1.1.
IER3	Scenarios 1 and 3: EHR or research network system sends redacted clinical research document to EDC. Reference action 7.2.5.1 part 1, 7.2.7.1, 7.3.6.1, IER8. Research protocol and confidentiality policy determines data elements to be redacted.
IER4	Scenarios 1 and 3: EDC returns pre-populated CRF to EHR or Research Network system. Ref action 7.3.3.2 part 1, IER9.
IER5	Scenarios 1 and 3: EHR or research network system sends completed case report form to EDC. Reference action 7.2.5.1 part 2, 7.3.3.2 part 2, IER10.
IER6	Scenario 2: EHR sends patient information (DR1, DR2, DR3, DR13) to registry. Reference action 7.2.3.1, IER1.
IER7	Scenario 2: Registry system sends subject identifier to EHR. Reference action 7.3.1.1, IER2.
IER8	Scenario 2: EHR sends clinical research document to registry system. Reference action 7.2.6.1 part 1, IER3
IER9	Scenario 2: Registry system returns partially pre-populated registry form to EHR. Ref action 7.3.3.2 part 1, IER9.
IER10	Scenario 2: EHR sends completed data form to Registry System. Reference 7.2.6.1 part 2, 7.3.3.2 part2, IHE5.
IER11	Scenario 1 and 3: EHR or research network system sends document (CCD, CRD) to electronic source document archive. Ref. action 7.3.5.4
IER12	Scenario 1 and 3: Receive laboratory information from central diagnostic facilities. Ref action 7.3.4.1
IER13	Scenario 1 and 3: Receive image information from central diagnostic facilities. Ref action 7.3.4.1
IER14	Send/Receive adverse event report to IRB, DSMB, sponsor, reviewer.

HITSP
Clinical Research Tiger Team

Status (cont.)

- Met with various TCs to address value case needs
  - SPI TC – Pseudonymize and anonymyze issues
  - CMHR – Clinical research document and workflow issues
- Identified the need for three new constructs
  - Clinical Research Document Component Construct
  - Clinical Research Workflow Component Construct
  - Clinical Research Anonymize Construct
- Developed the new Clinical Research Interoperability Specification
  - (HITSP IS158)
  - Draft currently under review by the Tiger Team

August 8, 2009
Version 1.0

HITSP Clinical Research Interoperability Specification

HITSP/IS158

HITSP
Healthcare Information Technology Standards Panel

Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Clinical Research Tiger Team

TABLE OF CONTENTS

1.0 INTRODUCTION 5
1.1 Interoperability Specification Overview 5
1.2 Document Scope 5
1.3 Copyright Permissions 6
1.4 Conformance 6
1.4.1 Conformance Criteria 6
1.4.2 Conformance Scoping, Subsetting and Options 6
1.4.3 Test Methods 6

2.0 REQUIREMENTS ANALYSIS 8
2.1 Synopsis of requirements 8
2.2 Protocol-driven sponsored research scenario 9
2.2.1 Protocol Driven Sponsored Research Information Exchange requirements 10
2.3 Registry Reporting scenario 11
2.3.1 Registry Information Exchange Requirements 11
2.4 Research Network scenario 12
Data Queries. Data are maintained within a security firewall of an organization. Queries can be made of the data from outside the firewall under controlled access. Users of different types can be granted different levels of access to the data. 12
2.4.1 Research network Information Exchange Requirements 12

3.0 DESIGN SPECIFICATION 14
3.1 Capabilities used in this interoperability specification 14
3.2 Capability Orchestration 15
3.2.1 CAPABILITY ORCHESTRATIONS 15
3.2.2 COMPONENT DATA FLOW DIAGRAM 17
3.2.3 Constraints on Required Capabilities 17

4.0 CAPABILITY GAPS 18
4.1 Gaps Where There Are No Standards 18
4.2 Standard Overlaps 18

5.0 APPENDIX 19
5.1 Data Elements 19

6.0 DOCUMENT UPDATES 28

Table 2-2 System Descriptions and Mapping to Stakeholders

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 located at the healthcare site.	Healthcare Delivery Organizations, Ancillary Entities, Clinicians, Care Delivery Actor
Electronic Data Capture (EDC) system	Referred to as 'Site Study Data System' in use case table 7.1. This system may handle data validation or it may be handled in a separate application.	Sponsor, Clinical Research Organization (CRO)
Clinical Data Management System (CDMS)	Clinical research repository where data are streamed for housing and cleansing. Out of scope; included for context only.	Sponsor, Clinical Research Organization (CRO)
Protocol Development System	System used to author protocols. Out of scope; included for context only.	Sponsor
Electronic Source Document Archive	A system that embodies RFD Form Archiver actor, and stores electronic source information on behalf of the site. Can be an add-on to the EHR, a standalone application at the site, or an application hosted by a trusted third party to the site.	Site
Data Safety Management Board (DSMB)	System to which adverse events are reported. Out of scope; included for context only.	Site
Institutional Review Board (IRB) system	Committee whose primary responsibility is to protect the rights and welfare of human research subjects through appropriate review and approvals prior to beginning research. Out of scope; included for context only.	Site
Reviewer system	"Individuals or organizations that review the final tabulated dataset once the study is complete."	Reviewer
Registry system	"For retrospective studies, such as epidemiologic studies, the core dataset may be exchanged with the clinical system which houses the EHR and sent to various patient registries or research databases." Relevant to scenario 2 only.	Sponsor, Clinical Research Organization (CRO)
Distributed Clinical Research Network system	An "intermediate database or data repository" that serves a network of healthcare and research sites. Relevant to scenario 3 only.	Site
Central Diagnostic system	"A central laboratory or imaging diagnostic center" to which research specific lab and image work is referred.	Labs
Analysis and Reporting System	Sponsor-based system. Performs analysis on study data.	Labs

Table 3-1 Capabilities Used

Capability	Capability Summary	IERs Satisfied
HITSP/CAP127 - Communicate Lab Results Document	This capability addresses interoperability requirements that support the communication of a set of structured laboratory results related to a patient in a context set by the source of the document who is attesting to its content. Non-ordering Providers of Care access historical laboratory results as documents and "copy-to" Providers of Care may receive document availability notifications to retrieve such lab report documents. Lab Report content creators shall support HITSP specified coded terminologies as defined by specific content subsets specified in this Capability for: General Laboratory Test Results; Microbiology Test Results This capability may use content anonymization.	IS158-IER12
HITSP/CAP128 - Communicate Imaging Information	This capability addresses interoperability requirements that support the communication of a set of imaging results (i.e., reports, image series from imaging studies) related to a patient in a context set. This is done by an Imaging System acting as the information source attesting to its content. This capability may use content anonymization.	IS158-IER13
HITSP/CAP135 - Retrieve and Populate Form	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 and Clinical Research 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: ° Pre-population for Public Health Case Reports from Structured Documents using CDA ° Pre-population for Quality Data from Structured Documents using CDA ° Pre-population of Clinical Research Reports from structured documents. ° No pre-population content Systems may optionally support the means to retrieve request for clarifications.	IS158-IER3 IS158-IER8 IS158-IER11
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 mind on participation or requests that data no-longer be made available because they have left the region.	IS158-IER1 IS158-IER2 IS158-IER3 IS158-IER4 IS158-IER5 IS158-IER6 IS158-IER7 IS158-IER8 IS158-IER9 IS158-IER10

Table 3.2 – Orchestration of Capabilities by Systems

System	System Role(s)	System Role Option	Capability	Optionality
Electronic Health Record (EHR) System	Form Filler	R	HITSP/CAP135 - Retrieve and Populate Form	R
	Consent Creator	R	HITSP/CAP143 - Manage Consumer Preference and Consents	R
Electronic Data Capture System	Content Consumer	O	HITSP/CAP 127 – Communicate Lab Results Document	O
	Imaging Document Consumer	O	HITSP/CAP 128 – Communicate Imaging Information	O
	Form Manager	R	HITSP/CAP135 - Retrieve and Populate Form	R
	Consent Consumer	R	HITSP/CAP143 - Manage Consumer Preference and Consents	R
Clinical Data Management System (CDMS)		Out of scope		Out of scope.
Protocol Development System		Out of scope		Out of scope
Electronic Source Document Archive	Form Archiver	O	HITSP/CAP135 Retrieve and Populate form	C(101)
Data Safety Management Board (DSMB)	Content Consumer	R	HITSP/CAP 127 – Communicate Lab Results Document	O
	Imaging Document Consumer	R	HITSP/CAP 128 – Communicate Imaging Information	O
	Consent Consumer	R	HITSP/CAP143 - Manage Consumer Preference and Consents	O
Institutional Review Board (IRB) system	Content Consumer	R	HITSP/CAP 127 – Communicate Lab Results Document	O
	Imaging Document Consumer	R	HITSP/CAP 128 – Communicate Imaging Information	O
	Consent Consumer	R	HITSP/CAP143 - Manage Consumer Preference and Consents	O
Distributed Clinical Research Network System	Form Filler	R	HITSP/CAP135 - Retrieve and Populate Form	R
	Consent Creator	R	HITSP/CAP143 - Manage Consumer Preference and Consents	R
Central Diagnostic system	Content Creator	R	HITSP/CAP 127 – Communicate Lab Results Document	O
	Send Document	R	HITSP/CAP 128 – Communicate Imaging Information	O

August 27, 2009
Version 0.0.1

HITSP Clinical Research Document Component

HITSP/C151

HITSP
Healthcare Information Technology Standards Panel

Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Care Management and Health Records Domain Technical Committee

TABLE OF CONTENTS

1.0 INTRODUCTION 7
1.1 Overview 7
1.2 Copyright Permissions 7
1.3 Reference Documents 7
1.4 Conformance 8
1.4.1 Conformance Criteria 8
1.4.2 Conformance Scoping, Subsetting and Options 9
2.0 COMPONENT DEFINITION 10
2.1 Context Overview 10
2.1.1 Component Constraints 10
2.1.2 Component Dependencies 11
2.2 Rules for Implementing 11
2.2.1 Data Mapping 11
2.3 Standards 12
2.3.1 Regulatory Guidance 13
2.3.2 Selected Standards 13
2.3.3 Informative Reference Standards 15
3.0 APPENDIX 17
4.0 DOCUMENT UPDATES 18

September 9, 2009
Version 0.0.1

HITSP Clinical Research Workflow Component

HITSP/C156

HITSP
Healthcare Information Technology Standards Panel

Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Care Management and Health Records Domain Technical Committee

TABLE OF CONTENTS

1.0 INTRODUCTION 5
1.1 Overview 5
1.2 Copyright Permissions 5
1.3 Reference Documents 5
1.4 Conformance 7
1.4.1 Conformance Criteria 7
1.4.2 Conformance Scoping, Subsetting and Options 7
1.4.3 Test Methods 7
2.0 COMPONENT DEFINITION 8
2.1 Context Overview 8
2.1.1 Component Constraints 8
2.1.2 Component Dependencies 8
2.2 Rules for Implementing 9
2.2.1 Data Mapping 9
2.2.1.1 Clinical Research Document 9
2.3 Standards 10
2.3.1 Regulatory Guidance 11
2.3.2 Selected Standards 11
2.3.3 Informative Reference Standards 11
3.0 APPENDIX 13

HITSP
Clinical Research Tiger Team

Next Steps

- Complete Review of data elements for new CR Anonymize construct *(Sept, 2009)*
- Work with CMHR TC to complete development of two new constructs *(Sept, 2009)*
- Work with SPI TC to complete development of new construct *(Sept-Oct, 2009)*
- Complete IS development and publication *(Oct, 2009)*
- Public comment period and comment resolution *(Nov-Dec 2010)*
- Finalize IS and submit to HITSP Panel for approval *(Jan 2010)*

Report from the Consumer Perspective Technical Committee

- Work streams
  - WG “A”: Common Device Connectivity & IS77 Remote Monitoring Gap
  - WG “B”: Medication Gaps
  - WG “C”: Medical Home
  - WG “D”: IS03/IS05 Gaps (Consumer Empowerment & Consumer Access to Clinical Info)
  - WG “E”: Consumer Preferences Tiger Team (in conjunction with SPI)

Report from the Consumer Perspective Technical Committee

- Common Device Connectivity & IS77 Remote Monitoring Gap (for System Data Exchange #2)
- Work plan & Status
  - Common Device Connectivity (CmDC)
    - TN905 Device Connectivity Technical Note draft v0.0.2 posted
    - Authoring assignments discussions underway
    - TN905 to be released for public comment…ideally pre-wave 1 cycle…10/1
    - Publication target date may be in jeopardy due to resource constraints
  - IS77 Gap (for System Data Exchange #2)
    - Pre-requisite IHE and Continua documentation requirements identified
    - Proposed timeline for the completion of these documents being vetted / finalized
    - Timeline harmonization for the completion of IS77 document to be finalized over the next 2 weeks
    - Preliminary estimate for IS77 document completion Mar-Apr 2010

Report from the Consumer Perspective Technical Committee

- Common Device Connectivity & IS77 Gap (for System Data Exchange #2)
- Capabilities
  - Common Device Connectivity (CmDC)
    - Will be described in TN905
  - IS77 Gap (for System Data Exchange #2)
    - CAP119 Structured Documents Using CDA (for SDE's other than SDE#2)
    - New capability expected for communication of measurements from the device intermediaries for SDE#2

Report from the Consumer Perspective Technical Committee

- Medication Gaps
  - Work plan & Status
    - Use pre-TT work to identify and consolidate additional requirements for Capabilities
    - Update Capabilities – coordinated with other TC work
    - Public review & comment on revised Capabilities – Webinar Sept 30
  - Capabilities
    - CAP117 Ambulatory Prescriptions / CAP118 Inpatient Prescriptions
    - CAP119 Structured Documents
    - CAP140 Benefits & Eligibility / CAP141 Referral Authorization
    - CAP143 Consumer Preferences
  - IS07 revision
    - Not within current deliverables

Report from the Consumer Perspective Technical Committee

- Medical Home
  - Work Plan & Status
    - Identify the Appropriate Documents
      - IS09
    - Generate a Problem List
    - Identify the Scope of a “Practice-based” Registry
      - IS06
  - Capabilities (So far)
    - CAP119 Communicate Structured Document
    - CAP120 Communicate Unstructured Document
    - CAP121 Communicate Clinical Referral Request
    - CAP126 Communicate Lab Results Message
    - CAP127 Communicate Lab Results Document
    - CAP128 Communicate Imaging Information
  - New IS

Report from the Consumer Perspective Technical Committee

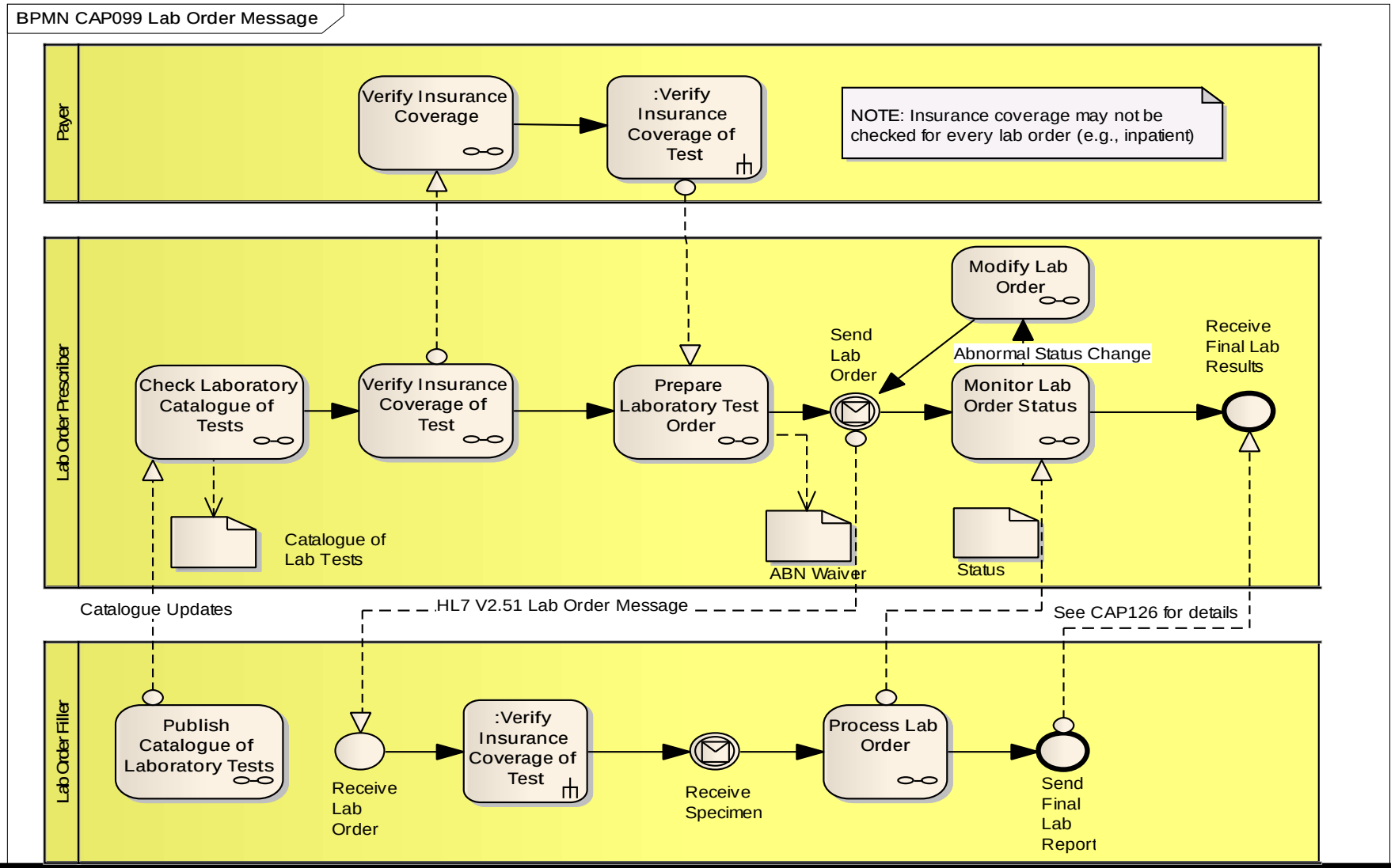
- IS03/IS05 Gaps (Consumer Empowerment)
  - Provider List
    - Ability of the consumer to generate a list of his providers in his PHR
    - RDSS has been prepared to document requirements
      - possible new constructs / capability
      - Collaboration with AFDTC, Provider Perspective TC on common requirements
  - PHR Location
    - Ability for a consumer who has two PHRs to send information from one of his PHRs to the other
    - Definition of Scope especially point-to-point interface
    - RDSS to be prepared to document requirements

Report from the Provider Perspective Technical Committee

- Current Focus
  - Lab Order Capability (CAP99) Status: Ready
- Next Focus (joint with CMHR)
  - Long Term Care Assessments
  - Clinical Notes
  - Order Sets
- Other Tasks
  - Update IS01 Lab Reports
  - Update IS04 Emergency Responder EHR

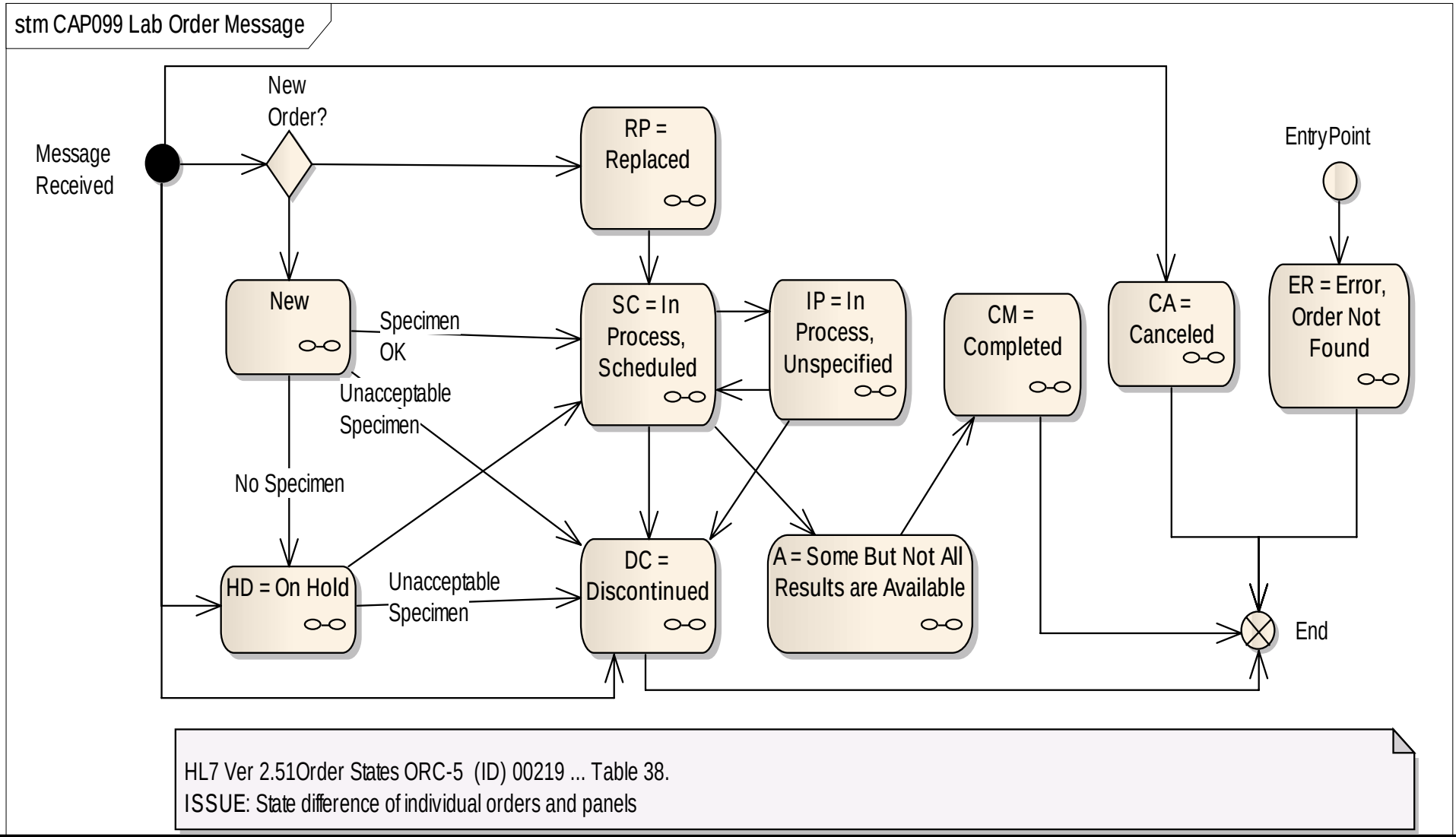
Report from the Provider Perspective Technical Committee

Notional Lab Order Workflow



Report from the Provider Perspective Technical Committee

Notional Lab Order States



Report from the Security, Privacy & Infrastructure Domain Technical Committee

- Primary Work items:
  - 4 Work Groups:

Consumer Preferences WG:	Leaders: Don Jorgenson, Jim Kragh Cochair oversight: Walter Suarez
Common Data Transport WG:	Leader: Geoff Pascoe Cochair oversight: Glen Marshall
De-Identification WG:	Leader: Bob Kaye Cochair Oversight: John Moehrke
Service Collaboration WG:	Leader: John Hummel Cochair Oversight: John Moehrke

- Full SPI-TC work items

Report from the Security, Privacy & Infrastructure Domain Technical Committee

Common Data Transport (CDT) Work Group

- Work Group meets weekly
- Reaching out to ONC and NHIN for clarification, input on stakeholder needs, and identification of work done by other groups in the CDT area.
- Deliverable type not yet defined (Service Collaboration, Technical Note, Capability,etc)

Report from the Security, Privacy & Infrastructure Domain Technical Committee

Consumer Preferences Work Group (CP-WG) in support of CP-Tiger Team

- There will be a separate report from CP-TT
- SPI CP-WG will be expected to address Security and Privacy technical requests from the TT and make any necessary changes to constructs (e.g. TP30 –Manage Consent Directives)

Report from the Security, Privacy & Infrastructure Domain Technical Committee

De-Identification Work Group:

- T24 (Pseudonymize): Major update to support provider and organization pseudonyms
- CXX: New construct for Anonymize for Clinical Research
- CXX: Potential new construct for Anonymize for Long Term Care Assessments

Report from the Security, Privacy & Infrastructure Domain Technical Committee

Service Collaboration Work Group:

- Generalize SCs to meet needs of existing and emerging Use Cases/Gaps/Extensions

Report from the Security, Privacy & Infrastructure Domain Technical Committee

Full SPI-TC work items

- TP20 (Access Control): Major update to include Cross-Enterprise Security and Privacy Authorizations – Extensive Access Control Markup Language – XSPA/XACML (when ready)
- C19 (Entity Identity Assertion): Update to include XSPA-SAML (Security Assertion Markup Language) - when ready - and Levels Of Assurance (LOA).
- TP50 (Retrieve Form for Data Capture): Major update to reflect new underlying standards in IHE RFD (Xforms and HTML forms)
- TN900: Update based on Security & Privacy Construct updates and SCs

Report from the Security, Privacy & Infrastructure Domain Technical Committee

Full SPI-TC work items (cont.)

- TP13 (Manage Sharing of Documents):
  - Review Document Metadata Subscription (DSUB) : This is new profile may fill a gap identified in TP13 for the ability to subscribe to topics about documents and get notified when new publications that meet the criteria. Possibly meets a gap for CDT.
  - Address IHE deprecation of XDS.a; review emerging standards for filling gaps:
    - Document Metadata Subscription (DSUB)
    - Multi-Patient Query (MPQ)
    - Cross-Community Patient Discovery (XCPD)

Report from the Security, Privacy & Infrastructure Domain Technical Committee

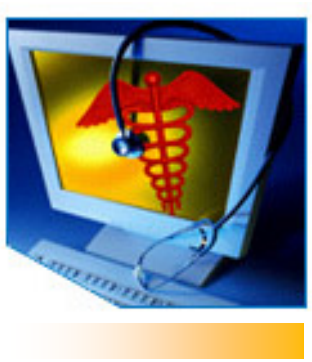
Full SPI-TC work items (cont.)

- Work with HL7 to support closing of gaps previously identified:
  - a) Review confidentiality Code proposals
  - b) Review Consent Directive Domain Analysis Model (DAM)
  - c) Review permissions catalog progress
  - d) Review Audit Service proposed ballot
  - e) Review Access Control Service progress
  - f) Security Cookbook

Report from the Security, Privacy & Infrastructure Domain Technical Committee

Full SPI-TC work items (cont.)

- Resolve outstanding comments in tracking system from TT work (may require updates to PIX/PDQ)



HITSP

Healthcare Information Technology Standards Panel

Report from the Consumer Preferences Tiger Team

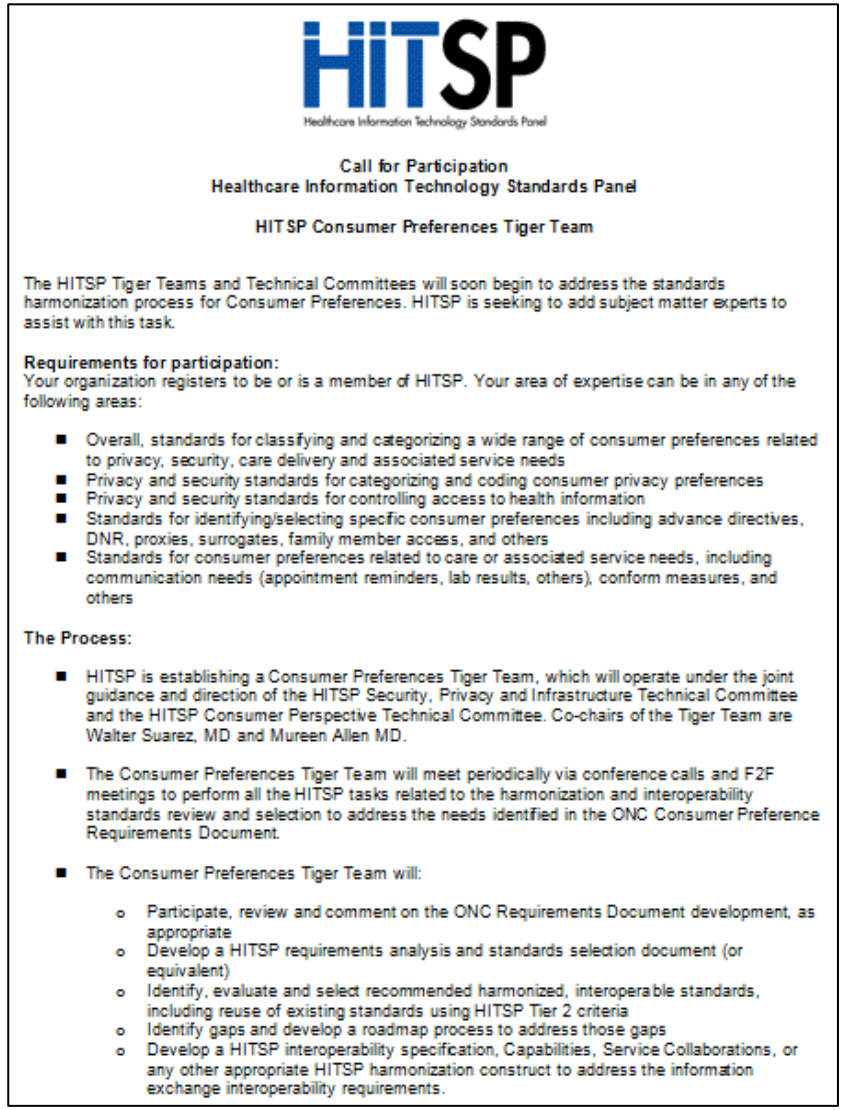
September 15, 2009

Presented by:

Walter Suarez, MD - Co-Chair, HITSP CP-TT
Mureen Allen, MD, FACP - Co-Chair, HITSP CP-TT

Tiger Team Organization

- Launched Tiger Team at the HITSP Face to Face meeting – August 25, 2009
- Prepared a “Call for Participation” and disseminated widely
  - Described purpose, terms of reference
  - Identified desired ‘qualifications’ for volunteers



HITSP
Healthcare Information Technology Standards Panel

Call for Participation
Healthcare Information Technology Standards Panel

HITSP Consumer Preferences Tiger Team

The HITSP Tiger Teams and Technical Committees will soon begin to address the standards harmonization process for Consumer Preferences. HITSP is seeking to add subject matter experts to assist with this task.

Requirements for participation:
Your organization registers to be or is a member of HITSP. Your area of expertise can be in any of the following areas:

- Overall, standards for classifying and categorizing a wide range of consumer preferences related to privacy, security, care delivery and associated service needs
- Privacy and security standards for categorizing and coding consumer privacy preferences
- Privacy and security standards for controlling access to health information
- Standards for identifying/selecting specific consumer preferences including advance directives, DNR, proxies, surrogates, family member access, and others
- Standards for consumer preferences related to care or associated service needs, including communication needs (appointment reminders, lab results, others), conform measures, and others

The Process:

- HITSP is establishing a Consumer Preferences Tiger Team, which will operate under the joint guidance and direction of the HITSP Security, Privacy and Infrastructure Technical Committee and the HITSP Consumer Perspective Technical Committee. Co-chairs of the Tiger Team are Walter Suarez, MD and Mureen Allen MD.
- The Consumer Preferences Tiger Team will meet periodically via conference calls and F2F meetings to perform all the HITSP tasks related to the harmonization and interoperability standards review and selection to address the needs identified in the ONC Consumer Preference Requirements Document.
- The Consumer Preferences Tiger Team will:
  - Participate, review and comment on the ONC Requirements Document development, as appropriate
  - Develop a HITSP requirements analysis and standards selection document (or equivalent)
  - Identify, evaluate and select recommended harmonized, interoperable standards, including reuse of existing standards using HITSP Tier 2 criteria
  - Identify gaps and develop a roadmap process to address those gaps
  - Develop a HITSP interoperability specification, Capabilities, Service Collaborations, or any other appropriate HITSP harmonization construct to address the information exchange interoperability requirements.

Tiger Team Organization

- Established the HITSP CP-TT Listserv and the TT working space inside the HITSP Portal
  - HITSP-CONSUMERPREF-TT@MAILLIST.ANSI.ORG
  - Must register as a member to the TT to join the listserv (Contact Allyn Clemons at aclemons@himss.gov)
- Identified and established weekly conference calls of the full TT: Wednesdays from 4-5 pm eastern
  - First call: Wednesday, Sept 16, 2009

Tiger Team Participation

- Large number of people joining
  - 65 confirmed members recruited in 5 days (9.9.09)
- Multiple perspectives represented:
  - Providers, payers, federal and state government, SDOs, vendors, associations
- Most coming from current members of SPI and Consumer Perspective TCs
- Look for representation from consumer advocate groups

Initial Priority Plan

- Initial work to focus on three priorities:
  - Review of Initial categorization of Consumer Preferences
  - Research, identify and document existing and emerging standards for Consumer Preferences
  - Review NHIN Factory Specs on Consumer Preferences
- Additionally
  - Review approaches used in other countries (i.e., Canada)

Next Steps

- Wednesday Sept 16 - Initial TT Call to focus on:
  - Organizational and process issues, SOW definition, overall timeline
  - Initial discussion on Categorization of Consumer Preferences
- Friday Sept 18 – Special session to focus on NHIN Factory Specs presentation (12:30 – 1:30 pm eastern)
- Wednesday Sept 23 – Continue discussion on Categorization of Consumer Preferences
- Wednesday Sept 30 – Initial review of existing/ emerging standards on consumer preferences; preliminary identification of gaps

Work Milestones and Timeline – Preliminary Outline

- September 2009: Organizational; review approach/ categorization of consumer preferences; gathering of existing/emerging standards; preliminary identification of gaps
- October/November 2009: Provisional standards requirements analysis, identification of gaps, based on draft ONC Requirements Document
- December 2009/January 2010: Revisions to preliminary standards analysis, based on final ONC Requirements Document
- February/April 2010: Selection of standards; roadmap to address gaps; new construct/capability/ service collaboration development; IS development

Report from the Care Management & Health Records Domain Technical Committee

- Current Work includes support for several Perspective Technical Committees
- Development of Clinical Note Details – Capability 119
- Complete the Implementation of Data Architecture ‘s ARRA TN903

Report from the Care Management & Health Records Domain Technical Committee

- Tiger Team Development
  - **Quality Measures – including HITEP II Modeling**
    2 constructs, 1 modified construct, 10-15 data elements, vocabulary
  - **Clinical Research – based on IHE QRPH**
    2 constructs , 10 data elements
- *Wave 1 Development*
  - **Laboratory Orders (Provider)**
    new vocabulary work; expecting new Construct and Data Elements;
  - **Newborn Screening (Population)**
    vocabulary; (re-use of laboratory Orders work)

Report from the Care Management & Health Records Domain Technical Committee

HITEP II Modeling Work

- **New Data Element/cda Section Creation**

  - Provider ID
  - Reason for Visit
  - Facility Name
  - Arrival Date/Time
  - Admit Date/Time
  - Discharge Disposition…

- **Data Element Gap Identification**

  - Death Information
  - Risk Mood
  - Patient Survey
  - Clinical Trial Enrollment
  - Patient Care Experience
  - Discharge Instructions…

- **Vocabulary Selection**

Report from the Care Management & Health Records Domain Technical Committee

- Clinical Note Details Development (Wave 1&2)
  - Simplified HITSP method to express HITSP Clinical Document Information
  - Clinical Note Details search capability through the use of defined Meta-data
  - Ability to add any type of Clinical Note Details using existing C83 CDA Sections
  - First implementation is expected to be Long Term Care Assessments (Wave 2)

Report from the Administrative and Financial Domain Technical Committee

- Completion of ARRA Data Architecture Work
  - Creation of HITSP Data Dictionary (Data Elements) C154 from C83
  - Conversion of Constructs, Transactions and Transaction Packages currently using Messaging Standards by applying TN903.
  - Addition of the Data Elements to the Data Dictionary discovered during the conversion

Report from the Care Management & Health Records Domain Technical Committee

- Creation of a HITSP Data Dictionary

Identifier	Name	Definition	Constraints
1.02	Person ID	An identifier that uniquely identifies the individual to which the exchange refers and connects that document to the individual's personal health record. Potential security risks associated with use of SSN or driver's license for this element suggest that these should not be used routinely	
1.03	Person Address	The current address of the individual to which the exchange refers. Multiple addresses are allowed and the work address may be a method of disclosing the employer	C154-[DE-1.03-1] The state part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.1 State C154-[DE-1.03-2] The postal code part of an address in the SHALL be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code C154-[DE-1.03-3] The country part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country

Report from the Care Management & Health Records Domain Technical Committee

- Message Standards HITSP Documents to be converted:
  - C36 - Lab Result Message
    C41 - Radiology Result Message
    C70 - Immunization Query and Response
    C72 - Immunization Message
    C39 - HITSP Encounter Message
    C74 - Remote Monitoring Observation
    T22 - HITSP Patient Demographics Query
    TP23 - HITSP Patient ID Cross-Referencing C34 - Quality Measures
    TP46 - Medication Formulary and Benefits Information
    T40 - Patient Health Plan Eligibility Verification
    T68 - Patient Health Plan Authorization Request and Response
    TP43 – Medication Orders
    T42 - Medication Dispensing Status
    T79 - Pharmacy to Health Plan Authorization Request and Response

Report from the Care Management & Health Records Domain Technical Committee

Example of HITSP HL7v2 Message Construct per TN903

CDC IG HL7 V2 Data Element	HITSP Data Element Identifier and Name	Optionality	Additional Specification
PID 3.3.2.6 - Mother's maiden name	1.12 Mother's Maiden Name	R2	
PID 3.3.2.7 - Date of birth	1.07 - Person Date of Birth	R	
PID 3.3.2.8 - Sex	1.06 - Gender	R	C154-[DE-1.06-1] Gender SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.1.2 V3 Administrative Gender

Report from the Administrative and Financial Domain Technical Committee

- Wave 1 Initiatives
  - Support Data Architecture Data Element Review
  - Prior Authorization
    - Capability 141
  - Technical Note for Administrative and Finance
  - Oasis / HAVE

Report from the Administrative and Financial Domain Technical Committee

- Wave 2 Initiative
  - Scheduling
    - Reviewing Scope and Requirements
    - Researching current Standards
    - IETF RFC 2445 – iCalendar
  - Provider Directory for Consumers
    - IS03/05 Gap
    - New Capability