HITSP

Healthcare Information Technology Standards Panel

Privacy and Security – Building Blocks for Healthcare Interoperability

The Privacy Symposium - The Sixteenth National HIPAA Summit

August 18-21, 2008 | Cambridge, MA

Presented by

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Co-Chair, HITSP Security, Privacy and Infrastructure Technical Committee

Learning Objectives

- This session will help participants better understand:
  - how HITSP is paving the way for interoperable healthcare information;
  - core concepts utilized by the Panel to harmonize standards for a specific business case as well as cross-cutting topics such as privacy, security, infrastructure and other supporting services; and
  - the relationship between and among the components of a HITSP Interoperability Specification (IS) — how they build upon one another and how they are shared across IS.

Agenda

- Introduction
- The HITSP Harmonization Framework
- Developing a HITSP Interoperability Specification (IS)
- Creating Interoperability Constructs to Address Use Case Requirements
- Overview of Base and Composite Standards for Privacy and Security
- Questions and Answers / Open Dialogue

Introduction: Steve's Story . . .

- Patient is a 26-year-old male coping with the long-term effects of a brain tumor that was removed during his childhood
- Examined by a specialist in Boston that participates in Massachusetts Share
  - MA-SHARE makes medical information available for exchange through a Regional Health Information Organization (RHIO)
- A CD-ROM of medical information was provided by the specialist to the patient
- Patient's local primary care physician could not open the files and does not have access to RHIO

Introduction: Steve's story (continued)

- **The Future** Healthcare in an interoperable world
  - With patient's consent, medical information can be seamlessly and securely exchanged between and among diverse systems, including providers and care settings where the patient has previously gone for testing or treatment
  - Care providers will have the most up-to-date records available because healthcare data will be retrieved electronically from its source

HITSP
Healthcare Information Technology Standards Panel

Overview

- HITSP is a volunteer-driven, consensus-based organization that is funded through a contract from the Department of Health and Human Services.

- The Panel brings together public and private-sector experts from across the healthcare community to harmonize and recommend the technical standards that are necessary to assure the interoperability of electronic health records.

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Deliverables and Mode of Operation

- The HITSP Standards Harmonization Framework
  - Identify a pool of standards for an AHIC (American Health Information Community) Use Case
  - Identify gaps and overlaps in the standards for this specific Use Case
  - Make recommendations for resolution of gaps and overlaps
  - Select standards using HITSP-approved Readiness Criteria
  - Develop **Interoperability Specifications (IS)** that use the selected standard(s) for the specific context
  - Test the IS

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Current Interoperability Specifications (IS)

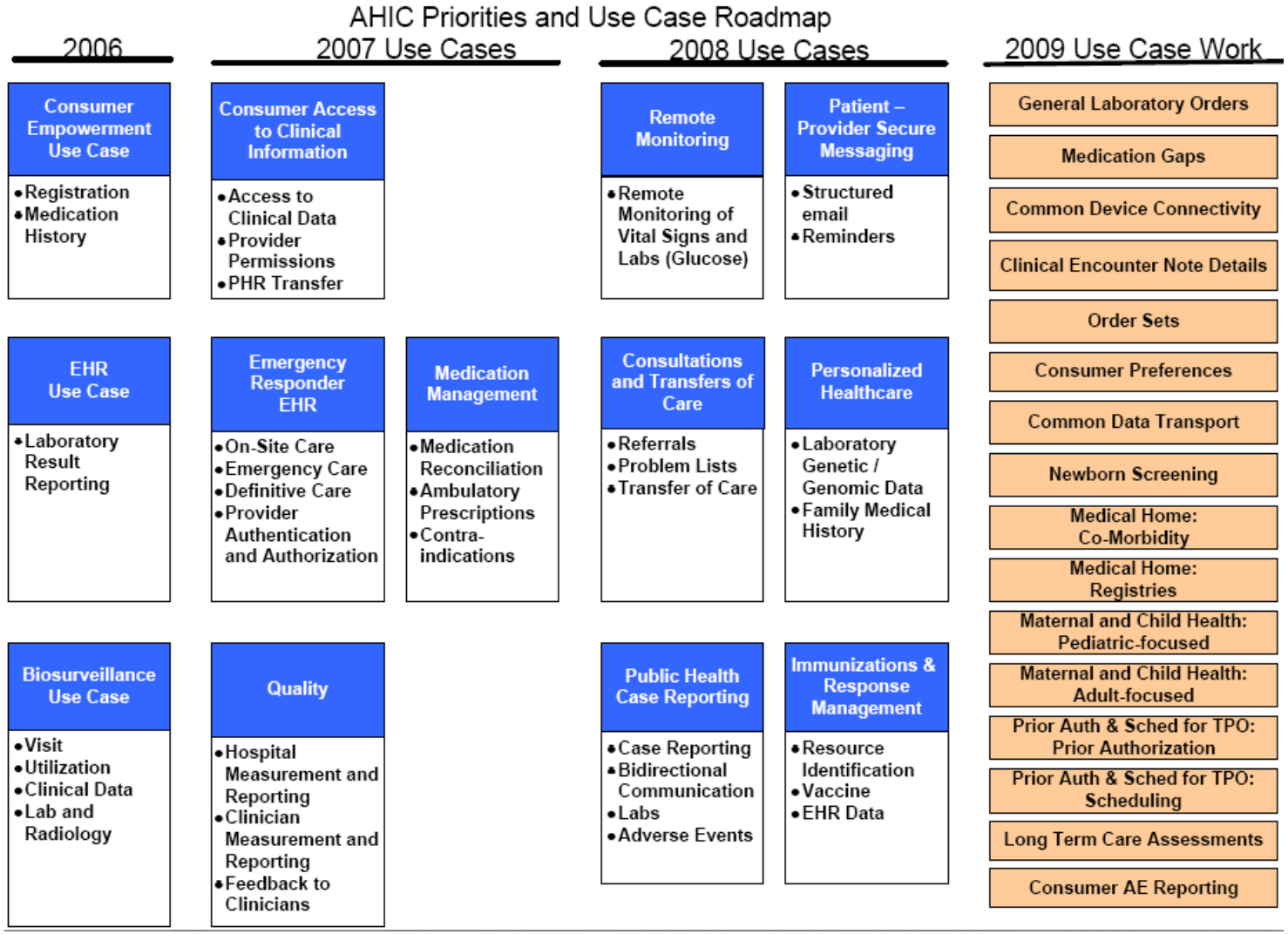
 IS 01	Electronic Health Record (EHR) Laboratory Results Reporting
 IS 02	Biosurveillance
 IS 03	Consumer Empowerment
 IS 04	Emergency Responder Electronic Health Record (ER-EHR)
 IS 05	Consumer Empowerment and Access to Clinical Information via Media
 IS 06	Quality
 IS 07	Medication Management

Overview HITSP Interoperability Specifications

AHIC Use Case

AHIC Use Cases

Define business and functional requirements



Source: American Health Information Community; Office of the National Coordinator for Health Information Technology. June, 2008

Overview HITSP Interoperability Specifications

AHIC Use Case

Interoperability Specification (IS)

- Identifies the framework that is a solution for business need (use case)
- Defines requirements including transactions and terminology
- Addresses multi-year roadmap as needed

HITSP Interoperability Specifications (IS)

- A HITSP IS represents a suite of documents that integrate and constrain existing **standards** (base or composite) to satisfy a Use Case.
- Each IS defines a set of “constructs” that:
  - specify how to integrate and constrain selected **standards** (base or composite) to meet the business needs of a Use Case; and
  - define a Roadmap to use emerging standards and to harmonize overlapping standards when resolved.

HITSP Interoperability Specifications (continued)

- Revisions and updates may mean that multiple versions of some Interoperability Specifications exist with differing status levels

- IS Status = State in the acceptance process
  - Released
    Panel approved for submission to HHS
  - Accepted
    Secretary of HHS has accepted for a period of testing
  - Recognized
    Secretary of HHS has recognized the IS for immediate implementation

Overview HITSP Interoperability Specifications

AHIC Use Case

Interoperability Specification (IS)

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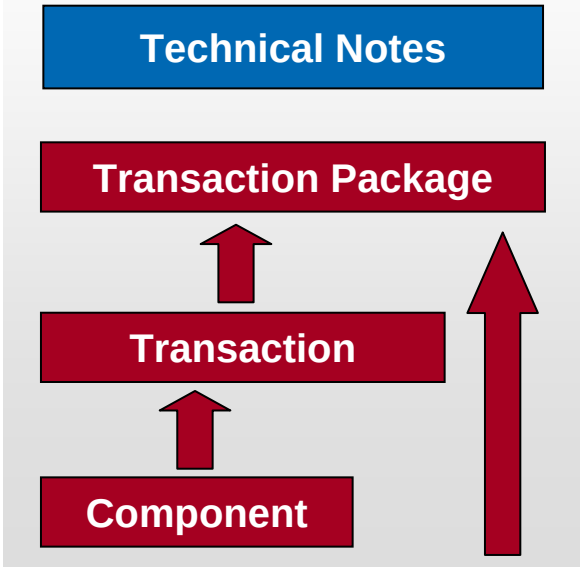
Constructs

available for reuse or repurposing



HITSP Constructs (In decreasing breadth of scope)

- Interoperability Specifications

  Integration of all constructs used to meet the business needs of a Use Case

- Transaction Packages

  Logical grouping of transactions

- Transactions

  Logical grouping of actions that use components and/or composite standards to realize the actions

- Components

  Logical grouping of base standards that work together, such as messaging and terminology

Overview HITSP Interoperability Specifications

AHIC Use Case

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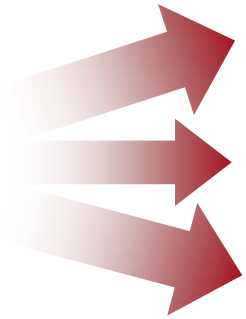
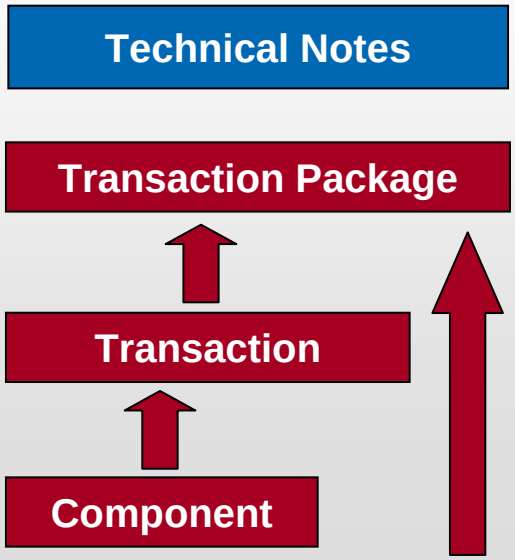


Constructs

available for reuse or repurposing



Composite Standard #1	Base Standard #2	Base Standard #3	Composite Standard #4	Base Standard #5	Base Standard #*n*	Base Standard #*n*

Standards

The building blocks of every Interoperability Specification

Standard A well-defined approach that supports a business process and . . .

- has been agreed upon by a group of experts;
- has been publicly vetted;
- provides rules, guidelines, or characteristics;
- helps to ensure that materials, products, processes and services are fit for their intended purpose;
- is available in an accessible format;
- is subject to an ongoing review and revision process.

Base Standard

- capable of fulfilling a discrete function

Composite Standards

- groupings of coordinated base standards

Examples

- Basic Specifications
- Implementation Guides
- Code Sets and Terminologies

Standards

"Real World" examples of Base and Composite Standards

- XML (base)
- IHE-XDS (composite)
- HL7-CCD (base)
- DICOM (base)
- LOINC (base)
- SNOMED-CT (base)
- NCPDP-Script (composite)
- etc.

Base Standard

- capable of fulfilling a discrete function

Composite Standards

- groupings of coordinated base standards

Examples

- Basic Specifications
- Implementation Guides
- Code Sets and Terminologies

Standards

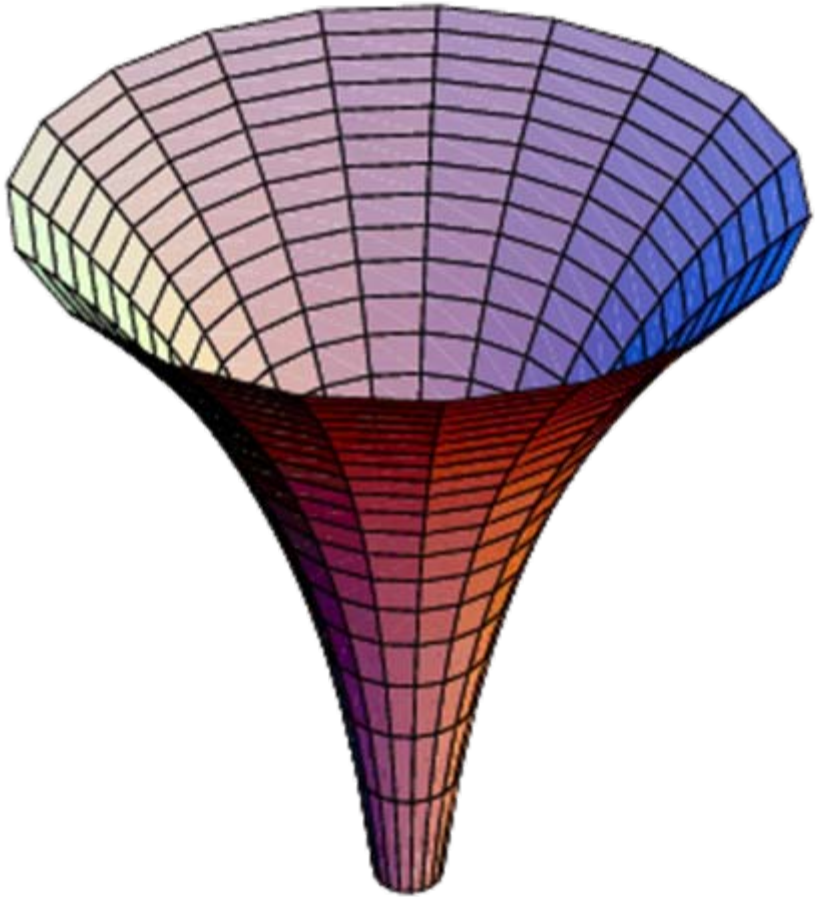
How standards are selected for an IS

- The standards selected for inclusion in the pool are examined using HITSP approved **Tier 1** and **Tier 2** Harmonization Readiness Criteria

- The standards required to support each major Use Case event are organized within an agreed upon standards taxonomy

Standards Readiness Criteria

Tier One



Suitability for purpose

Organization and process

Costs

Life cycle maturity

Other

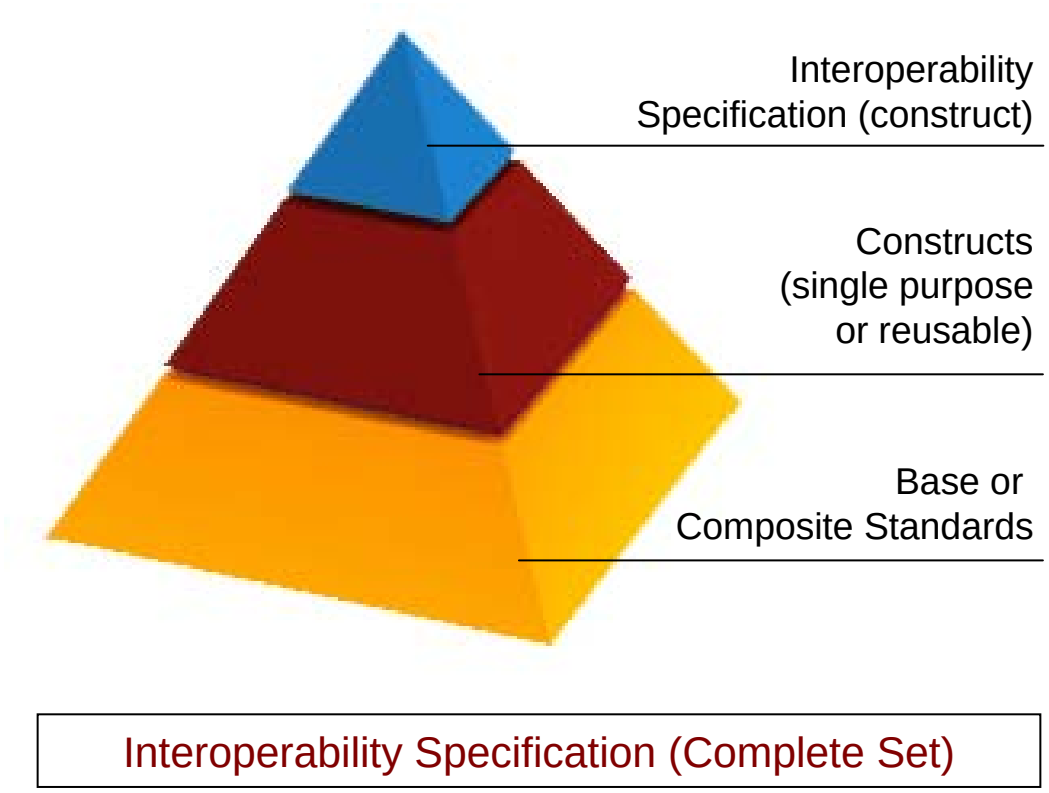
Standards Readiness Criteria

Tier Two

- **Suitability**
  The standard is named at a proper level of specificity and meets technical and business criteria of use case
- **Compatibility**
  The standard shares common context, information exchange structures, content or data elements, security and processes with other HITSP harmonized standards or adopted frameworks as appropriate
- **Preferred Standards Characteristic**
  Approved standards, widely used, readily available, technology neutral, supporting uniformity, demonstrating flexibility and international usage are preferred
- **Standards Development Organization and Process**
  Meet selected criteria including balance, transparency, developer due process, stewardship and others.
- **Total Costs and Ease of Implementation**
  Deferred to future work

Summary HITSP Interoperability Specifications

- A complete IS set provides a framework that defines
  - a hierarchy of constructs
  - the role of each construct
  - the relationship of one construct to another within the context of a specific Use Case

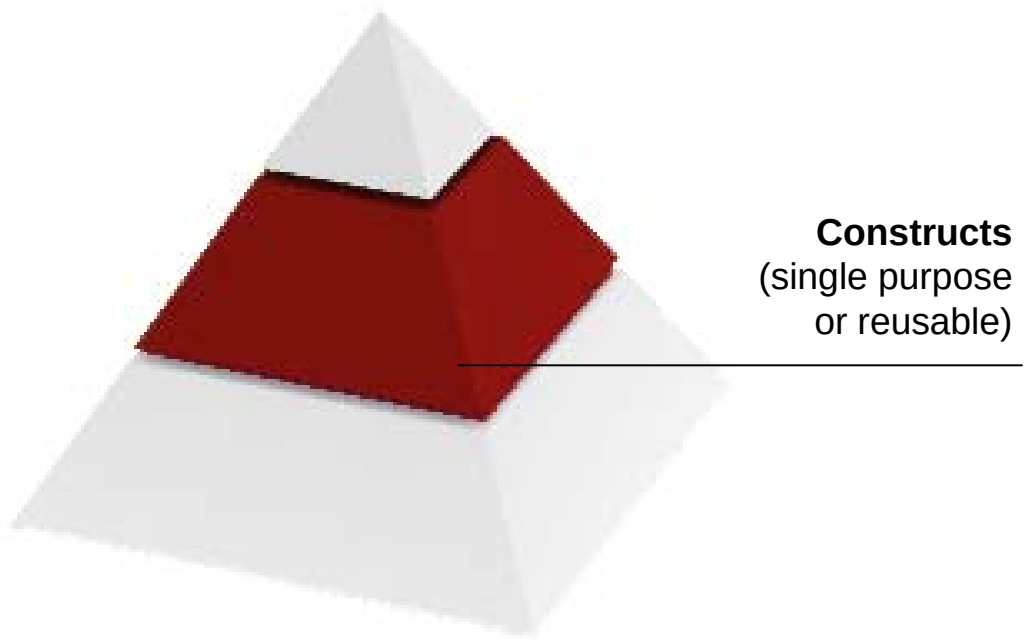


HITSP Interoperability Specifications

Construct Re-Use and Re-Purpose

- **Re-Use**
  Applying an existing construct to more than one IS

- **Re-Purpose**
  Updating a construct to meet the needs of a new Use Case



KEY BENEFIT

- ‘Re-use and re-purpose’ speeds the rapid roll out of Harmonized Standards

HITSP Interoperability Specifications

Construct Re-Use and Re-Purpose (continued)

- No need to “reinvent the wheel” every time there is a new Use Case
- The applicability of the constructs across Use Cases is done consistently
- Based on requirements of Use Cases, new constructs might still be needed because existing constructs do **not** address the newly defined need

- **REAL-WORLD EXAMPLE:**

  Security, Privacy and Infrastructure (SPI)

Security, Privacy and Infrastructure (SPI) and Healthcare Information Interoperability

- **Security**

  Elements such as consistent time, secure communications channel, entity identity assertion, and others

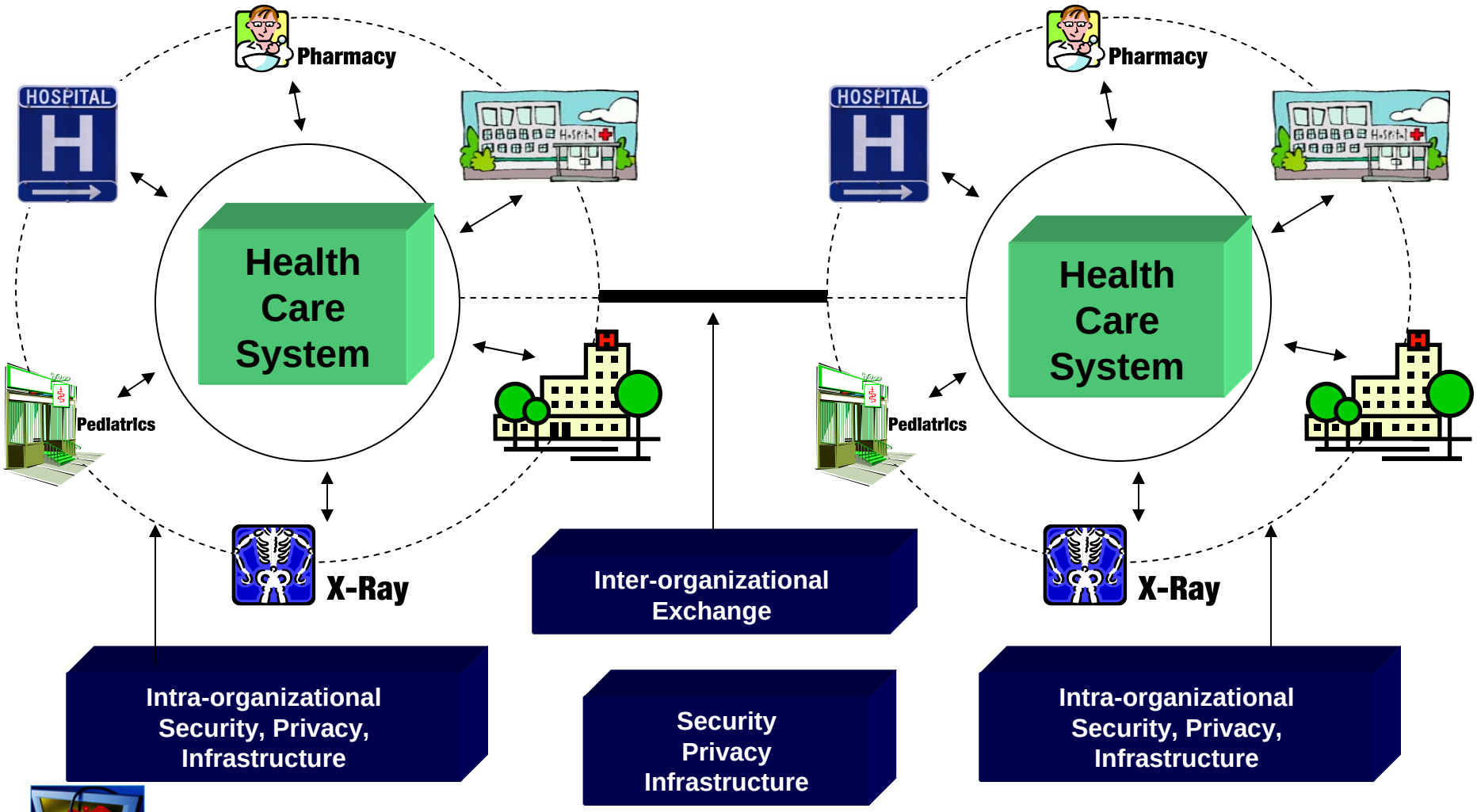
- **Privacy**

  Elements related to capturing and reporting consent directives electronically

- **Infrastructure**

  Structural elements of the exchange health information, such as querying for existing data or notification of document availability

SPI and Healthcare Information Interoperability



Security and Privacy

- Medical records contain some of the most sensitive information about a person.
- The privacy and security of health information are central to the doctor-patient relationship.
- Many laws and regulations address the topic:
  - Federal: HIPAA, Privacy Act, Education Records Law, Mental Health Records Laws, Public Health Information Laws
  - State: There is a patchwork of varying types and levels of state privacy laws, though few address health privacy and security in a comprehensive fashion

Security and Privacy (continued)

- HITSP focuses on Security and Privacy between entities, not within an entity.

- Common Security and Privacy Constructs are used across the HITSP Interoperability Specifications.

- **KEY BENEFIT**

  Organizations do **not** need to redo internal security procedures when implementing HITSP IS

Infrastructure

- Most interoperability uses the same common types of mechanisms for exchanging information.
- Instead of “reinventing the wheel” each time, common infrastructure constructs are reused.
- Example
  - Many specifications use document sharing as a means of exchanging information.
  - One of the Infrastructure Constructs is a Transaction Package called “Manage Sharing of Documents.”
  - This Construct is used in many different Interoperability Specifications.

HITSP SPI Constructs

- Provide Entity Identity Assertions
- Managing consumer privacy Consent Directives
- Establishing and manage Access Controls
- Ensuring Management of Document Sharing
- Utilize a Secure Communication Channel
- Implementing Nonrepudiation of Origin
- Collecting/communicating Security Audit Trails
- Consistent use and control of system Time
- Provide Patient Demographics Query
- Ensure Document Reliable Exchange
- Establish Patient ID Cross-Referencing
- Provide Notification of Document Availability
- Utilize Secure Web Connection
- Allow secure Transfer of Documents on Media
- Support Query for Existing Data
- Support the ability to Retrieve Form for Data Capture
- Provide ability to Pseudonymize and Anonymize data

HITSP SPI Constructs

Use across HITSP IS

SPI Constructs	IS01	IS02	IS03	IS04	IS05	IS06	IS07	ISXX
Entity Identity Assertion (C19)	✓	✓	✓	✓	✓	✓	✓	✓
Consent Directives (TP30)	✓	✓	✓	✓	✓	✓	✓	✓
Access Controls (TP20)	✓		✓	✓	✓	✓	✓	✓
Management of Document Sharing (TP13)	✓	✓	✓	✓		✓	✓	✓
Secure Communication Channel (T17)	✓	✓	✓	✓		✓	✓	✓
Non-repudiation of Origin (C26)	o	✓	✓	o	o	✓	o	o
Collect/Communicate Security Audit Trail (T15)	✓	✓	✓	✓	✓	✓	✓	✓
Consistent Time (T16)	✓	✓	✓	✓	✓	✓	✓	✓
Patient Demographics Query (T23)	✓		✓	✓	✓	✓	✓	✓
Document Reliable Exchange (T31)						✓		✓
Other SPI constructs…..	✓	✓	✓	✓	✓	✓	✓	✓

ISXX = Initial Assessment of Applicability of SPI Constructs to New 2008 Use Cases

O = Construct not required but optionally available for use

HITSP SPI Constructs

Four examples of how HITSP IS Constructs help "Steve"

- Security: T17 – Secured Communication Channel
- Infrastructure: TP13 – Manage Sharing of Documents
- Infrastructure: T23 – Patient Demographic Query
- Privacy: TP30 – Manage Consent Directives

Learn more about HITSP's activities in the area of

Security, Privacy and Infrastructure

Webinar 7: Thursday, August 21, 2008 — 2:00-3:30 pm EDT

HITSP SPI Constructs

Example One: Security

- **T17 HITSP Secured Communication Channel Transaction**

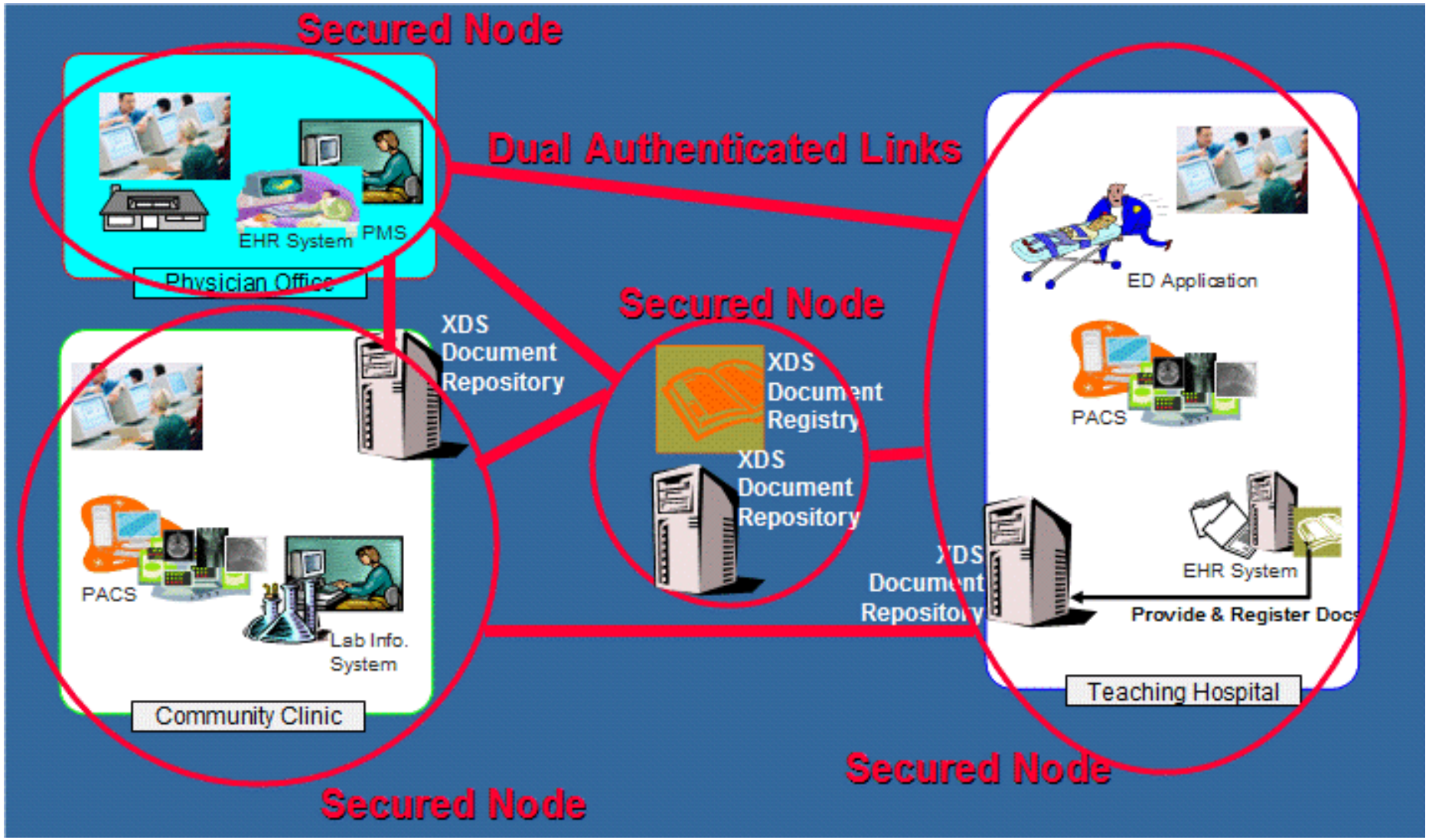
  The Secured Communication Channel Transaction provides the mechanisms to ensure the authenticity, integrity, and confidentiality of Transactions, and the mutual trust between communicating parties. It supports both application and machine credentials, and user machines (user nodes).

  - **Concept**

    To ensure the authenticity, the integrity, and the confidentiality of transactions, and the mutual trust between communicating parties.

Steve's information is kept secure as it moves from one provider to another.

T17 HITSP Secured Communication Channel Transaction



HITSP SPI Constructs

Example Two: Infrastructure

- **TP 13 HITSP Manage Sharing of Documents Transaction Package**

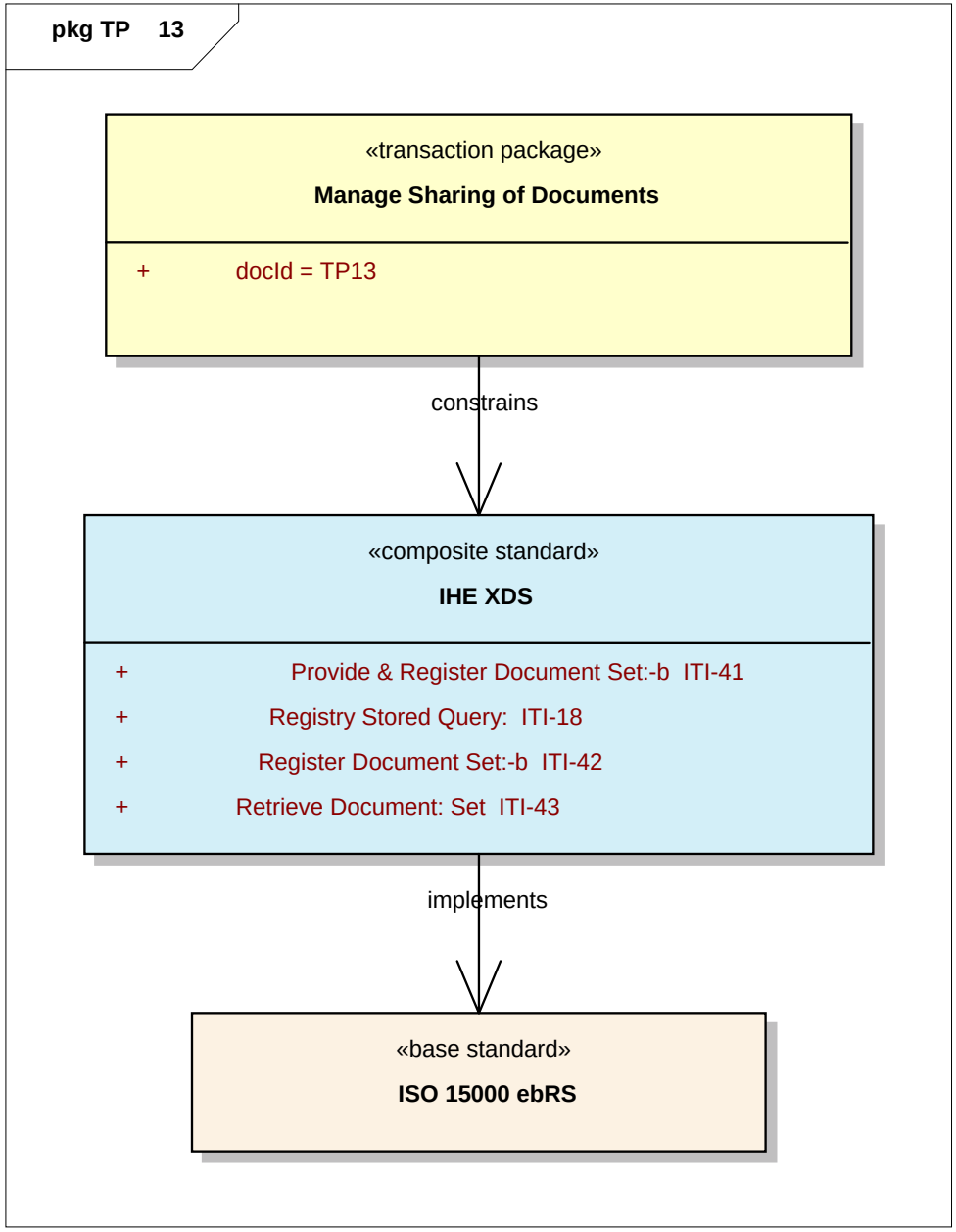
  This Transaction Package supports the sharing of patient records in the form of source attested objects called documents. A healthcare document is a composite of structured and coded health information, both narrative and tabular, that describes acts, observations and services for the purpose of exchange. No assumption is made by this construct in terms of the format and structure of the content of documents shared.

  - **Concept**

    Defines the methodology and metadata requirements for the registration, storage and retrieval of documents across repositories.

  - Sharing of source attested documents, document content neutral, document registry, document repositories distributed or centralized.

Steve's doctors are able to get his medical record information on demand.


pkg TP 13
«transaction package»
Manage Sharing of Documents
+ docId = TP13
constrains
«composite standard»
IHE XDS
+ Provide & Register Document Set:-b ITI-41
+ Registry Stored Query: ITI-18
+ Register Document Set:-b ITI-42
+ Retrieve Document: Set ITI-43
implements
«base standard»
ISO 15000 ebRS

HITSP SPI Constructs

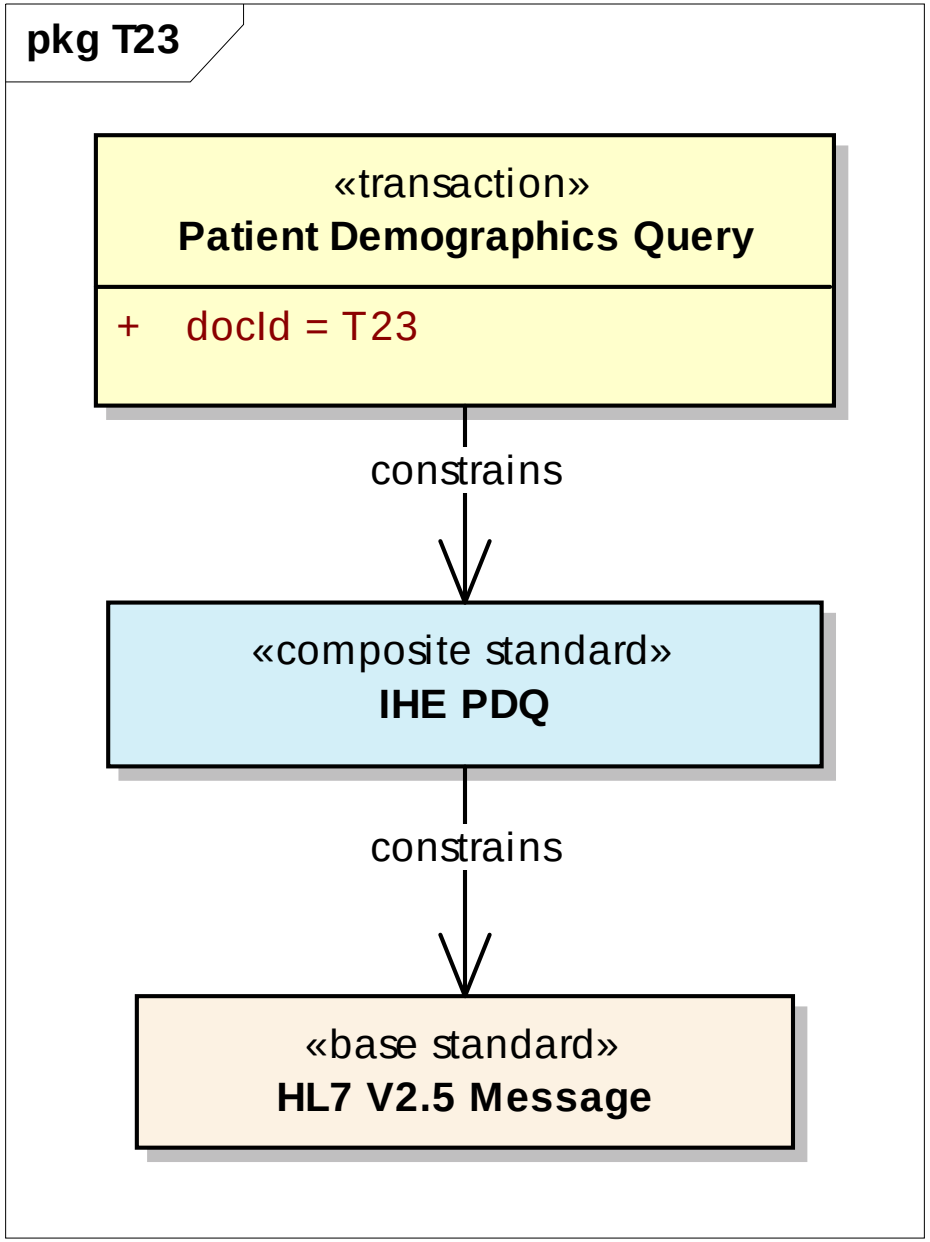
Example Three: Infrastructure

- **T23 HITSP Patient Demographics Query Transaction**

  This PDQ Transaction is intended to provide a ‘list patients and their demographics’ query / ‘patient(s) and their demographics identified’ response message pair (QBP^Q22, RSP^K22) for use wherever such needs exist. This Transaction document extracts the Health Level Seven (HL7) version 2.5 Query and Response data mapping. The underlying basis for this extraction can be found in the Integrating the Healthcare Enterprise IT Infrastructure Technical Framework, Volume 2 (ITI TF-2), Revision 3.0: “Patient Demographics Query.”

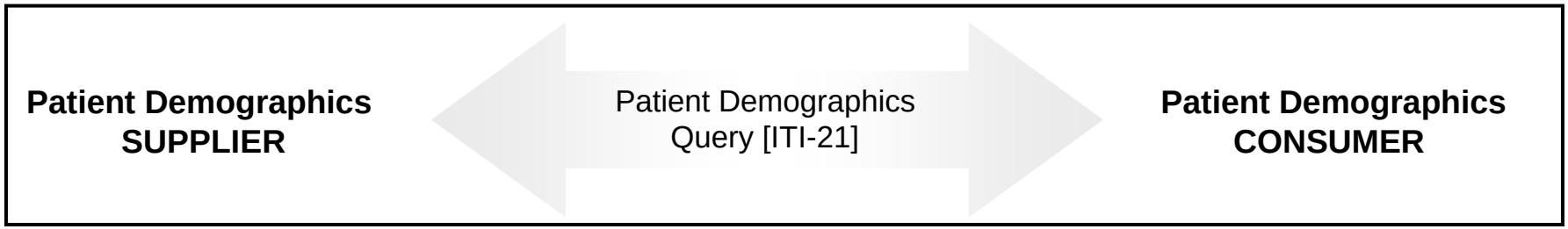
  - **Concept**

    Defines the methodology for identifying a patient (or list of patients) that match a provided set of patient demographics


pkg T23
«transaction»
Patient Demographics Query
+ docId = T23
constrains
«composite standard»
IHE PDQ
constrains
«base standard»
HL7 V2.5 Message

T23 – Patient Demographics Query

- One Transaction – Two Systems (actors)
  - **Patient Demographic Supplier**
    Manages the demographics traits of persons
  - **Patient Demographics Consumer**
    Issues a *Patient Demographics Query* to the *Patient Demographics Supplier* with some person traits, and receives in response one or more matching persons with those respective traits.



HITSP SPI Constructs

Example Four: Privacy

- **TP30 HITSP Manage Consent Directives Transaction Package**

  The Manage Consent Directives Transaction Package provides the mechanism to capture and transmit in a codified way a consumer's decisions regarding the collection, access, use and disclosure of his/her individually identifiable health information. Decisions affect what information can be collected, accessed, used or disclosed, by whom, to whom, when, how, and for what purpose. The transactions described in this construct are intended to be carried out by HITSP/TP13 - Manage Sharing of Documents.

  - **Concept**

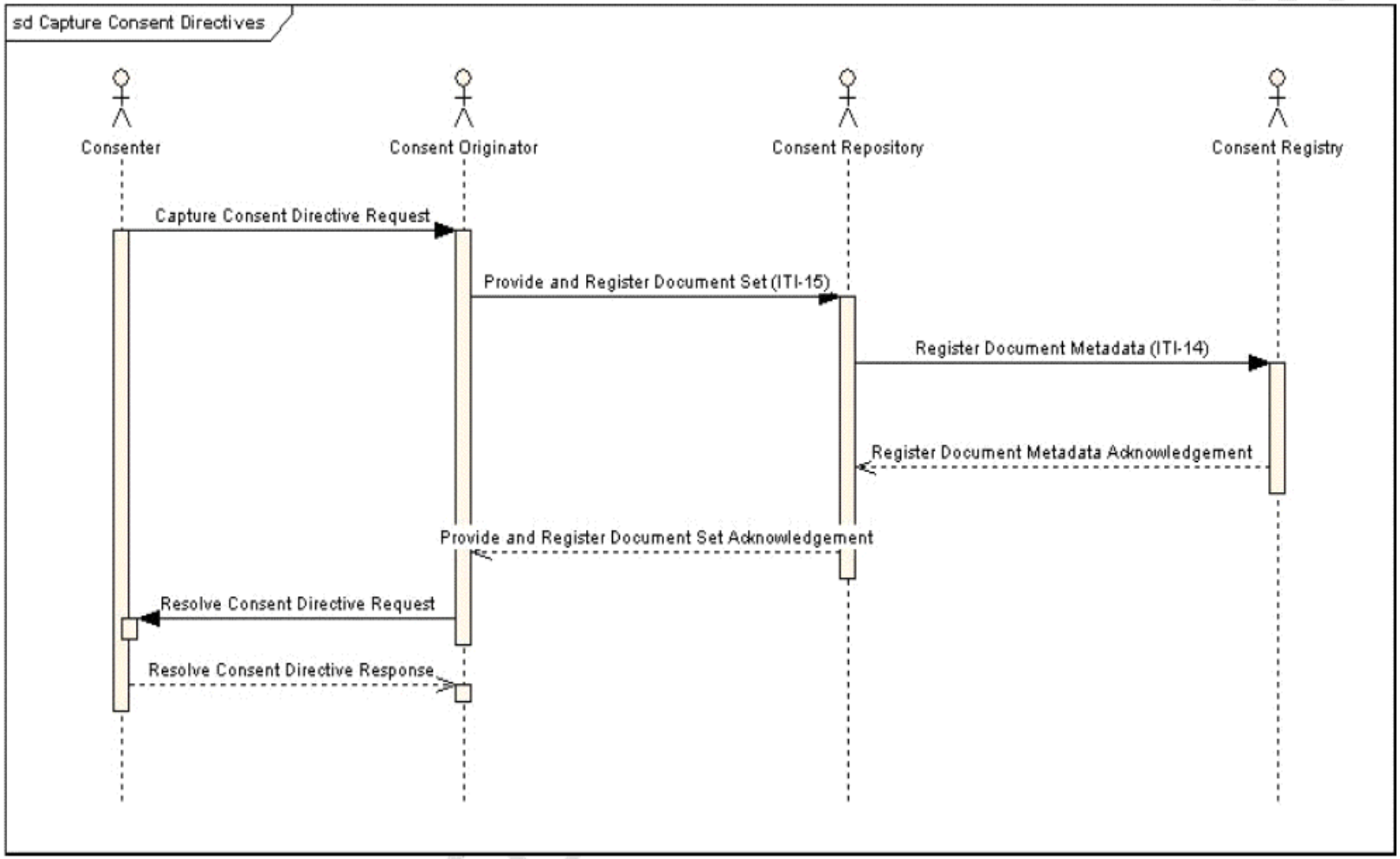
    To capture, manage and communicate information privacy rights granted or withheld by a consumer to one or more identified entities in a defined role to access, collect, use or disclose individually identifiable health information (IIHI).

    Also supports the delegation of the patient's right to consent.

Steve makes decisions about who can access what health information about him and for what purpose and communicates those to his provider.

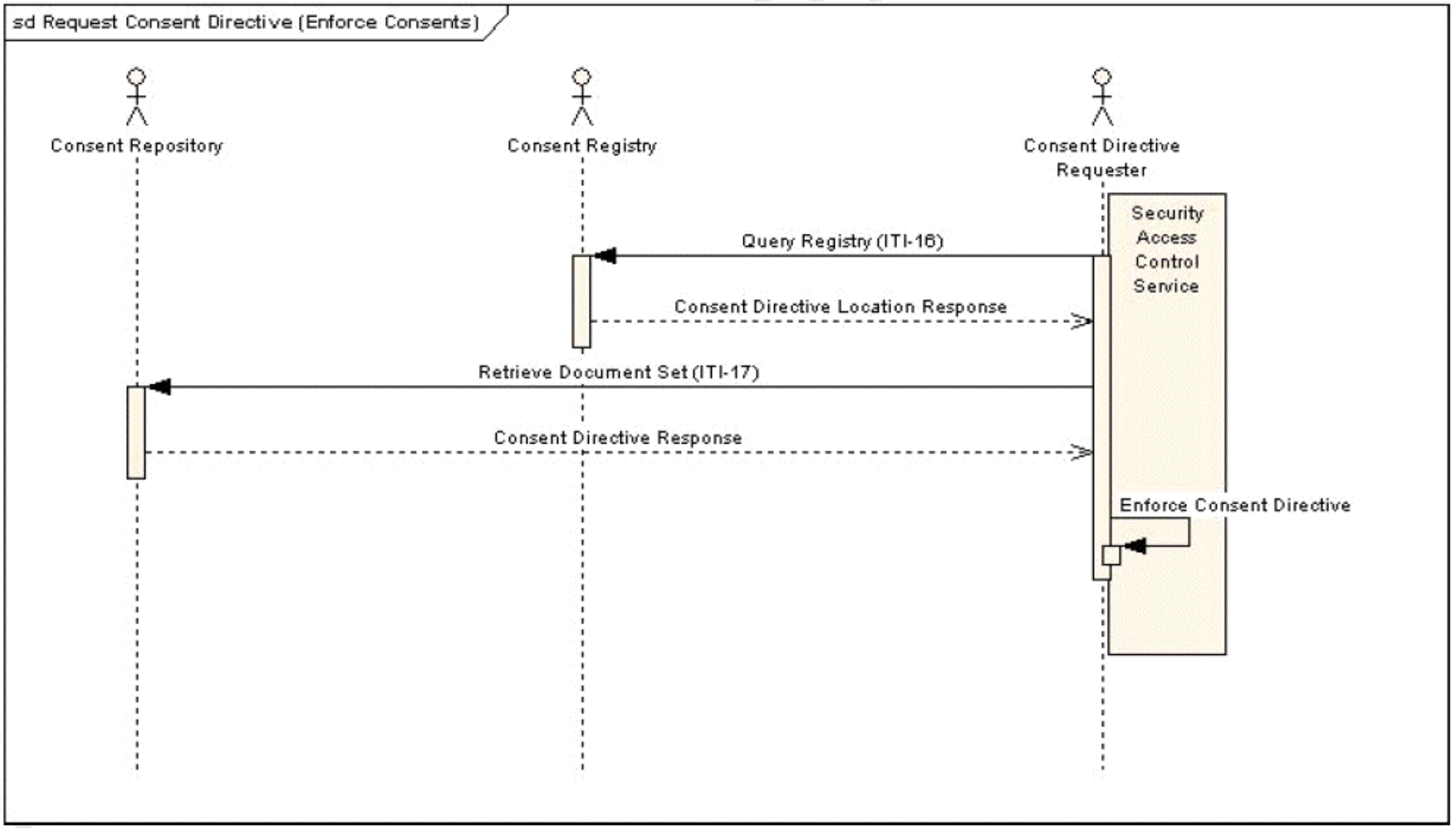
T30 HITSP Manage Consent Directives

High Level Sequence Diagram – Capture Consent Directives



T30 HITSP Manage Consent Directives

High Level Sequence Diagram – Request Consent Directives



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How YOU can become involved

- Use or specify HITSP Interoperability Specifications in your HIT efforts and in your Requests for Proposals (RFPs)
- Ask for CCHIT certification
- Leverage Health Information Exchanges to promote HITSP specifications to make connections easier in the future
- Ask . . . Is there a HITSP standard we could be using?
- Get involved in HITSP . . . Help shape the standards

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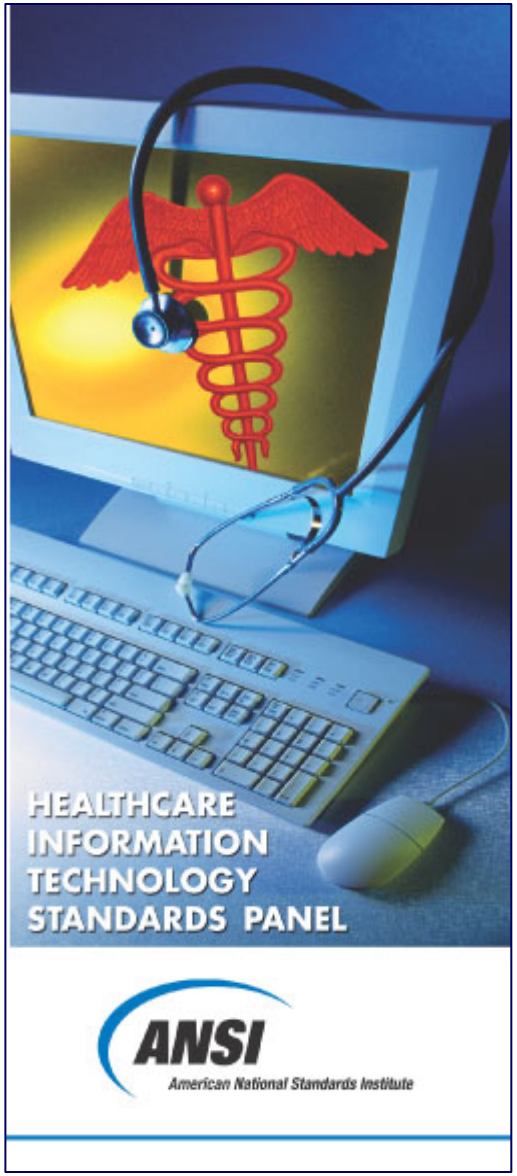
How YOU can become involved

Learn more about specific HITSP activities through its Summer, 2008 webinars:

Webinar 1 **Standardizing How We Share Information in Healthcare: An Introduction to HITSP** **(Completed in July/August – check the archived webinar library!)**		**Webinar 6** **Quality (Postponed)**	
Webinar 2 **HITSP Foundational Components** **(Completed in July/August – check the archived webinar library!)**		**Webinar 7** **Security, Privacy and Infrastructure** **(Completed in July/August – check the archived webinar library!)**	
Webinar 3 **Consumer Access to Clinical Information** **(Completed in July/August – check the archived webinar library!)**		**Webinar 8** **EHR and Emergency Response** Thursday, September 4, 2008 — 2:00-3:30 pm EDT	
Webinar 4 **Biosurveillance** **(Completed in July/August – check the archived webinar library!)**		**Webinar 9** **Medication Management** Thursday, September 18, 2008 — 2:00-3:30 pm EDT	
Webinar 5 **Electronic Health Record (EHR) and Lab Reporting** **(Completed in July/August – check the archived webinar library!)**		**www.HITSP.org/webinars**	



Join HITSP in developing a safe and secure health information network for the United States.

Visit **www.hitsp.org** or contact . . .

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Building Blocks for Healthcare Interoperability

An Overview of Core Concepts Utilized by HITSP in the Standards Harmonization Process