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HITSP Interoperability Specification: Pseudonymize Transaction

HITSP/IST-24

Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Biosurveillance Technical Committee

DOCUMENT CHANGE HISTORY

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1.0 FOREWORD

Healthcare Information Technology Standards Panel (HITSP) is a multi-stakeholder coordinating body designed to provide the process within which affected parties can identify, select, and harmonize standards for communicating healthcare information throughout the healthcare spectrum. HITSP functions as a partnership of the public and private sectors and operates with a neutral and inclusive governance model administered by the American National Standards Institute. The goal of the Panel is to:

- Facilitate the development of harmonized interoperability specifications and information policies, including SDO work products (e.g. standards, technical documents). These policies, profiles and work products are essential for establishing privacy, security and interoperability among healthcare software applications.
- Coordinate, as appropriate, with other national, regional and international groups addressing healthcare informatics to ensure that the resulting standards are globally relevant.
- Be use-case driven, utilize information from stakeholders and base its decisions on industry needs.

The HITSP shall serve the public good by working to ensure that the combined work of various healthcare information standards organizations supports interoperability, accurate use, access, privacy and security of shared health information.

In order to advance the goal of expanding harmonized interoperability specifications and information policies, HITSP was tasked with developing interoperability specifications for three main use cases “breakthroughs areas” in which specific, near term value to the health care consumer could be realized. The harmonized use case areas are:

1.	Biosurveillance	Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.
2.	Consumer Empowerment	Allow consumers to establish and manage permissions access rights and informed consent for authorized and secure exchange, viewing, and querying of their linked patient registration summaries and medication histories between designated caregivers and other health professionals.
3.	Electronic Health Record	Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care.

The interoperability specification provides a detailed mapping of existing standards and specifications such as implementation guides, integration profiles to actions and actors that satisfy the requirements

imposed by the relevant use cases. It identifies and constrains standards where necessary, and creates groupings of specific actions and actors to further describe the relevant contexts. Where gaps and overlaps are identified, the interoperability specification provides recommendations and a roadmap for corrections to be made.

2.0 INTRODUCTION

The purpose of this Transaction is to describe a framework for including a Pseudonymization Service in use cases that require the use of "dummy" or pseudo references to specific patients. Pseudo identifiers are intended to allow accessibility to clinical information while safeguarding any information that may compromise the privacy of the individual patient. Using pseudo identifiers can assist in compliance with HIPAA regulations regarding suppression of patient identification information.

This Transaction can be used in conjunction with Transaction HITSP/IST-22, *HITSP Interoperability Specification: Patient ID Cross-Referencing (PIX) and Patient Identity Feed Transactions.* The operation of the Pseudonymization Service in the context of the PIX Actors is described in the present document.

Use cases for patient identification suppression are described in Section 4.1, "Context Overview."

2.1 OVERVIEW

Pseudonymization: The process of supplying an alternative identifier that permits a patient to be referred to by a key that suppresses his/her actual identification information.

Related Documents	Document Description	Document Name and Location
HITSP/IST-22	HITSP Interoperability Specification: Patient ID Cross-Referencing (PIX) and Patient Identity Feed Transactions	

2.2 AUDIENCE

The interoperability specification is designed to be used by analysts who need to understand the interoperability requirements for the described use case, and by implementers working to develop interoperable applications. Understanding and using the relevant interoperability set of specifications is a key requirement for establishing interoperability compliance.

This transaction is intended to be used by implementers who need to transmit patient-specific clinical information while suppressing data that could be used to identify a specific patient or patients. It is also intended to illustrate how an entity responsible for the maintenance of a master list of patient identifiers, such as the PIX Manager described in Transaction HITSP/IST-22, can integrate a pseudonymization service into its information architecture.

2.3 TERMS AND DEFINITIONS

The definitions used for the purposes of this document can be found in the glossary. Refer to section 6.0 for a link to the Interoperability Specification of the Common Terms and Definitions Documents.

2.4 CONVENTIONS

This specification uses the following to convey the full descriptions and usage of standards:

UML sequence and activity diagrams

In these diagrams, the actors and transactions are highlighted within the framework of the specific scenario or context. The actors involved in the specified use-scenario or context are mapped out, and the interactions between each action and actor for a particular context, and the flow of data are provided through the use of arrows. Diagrams are named according to the section in which they reside, and will use the following naming convention:

Figure <section number>-<consecutive number for the diagram, e.g. 1, 2, 3, etc.>. <Short name/description of diagram>. For example, a diagram residing in section 3.1.3 showing the Actor Interactions for the Send Lab Results transaction package is named:

Figure 3.1.3-1. Send Lab Results Transaction Package

Tables

Tables are used to indicate standards categorizations, as well as dependencies and constraints between constructs. Tables are named according to the section in which they reside, and will use the following naming convention:

Table <section number>-<consecutive number for the table, e.g. 1, 2, 3, etc.>. <Short name/description of table>. For example, a table residing in section 2.7.1 showing the Dependencies between the transactions for the Send Lab Results transaction package is named:

Table 2.7.1-1. Send Lab Results Transaction Package dependencies

References

When references are made to another section within an Interoperability Specification a section number is used by itself. When references are made to other constructs that are related to the Interoperability Specification, such as Transaction Packages, Components or Composite Standards, the HITSP document short name and section number are displayed as follows:

<HITSP Document short name or Composite Standard Short Name>-<Volume Number>: <section number>

where:

<HITSP document short name> is a short designator for the construct (e.g. HITSP/ISTP-013)

<Composite Standard Short Name> is a short designator for the composite standard (e.g. IHE-ITI TF)

<Volume Number> is the applicable volume within the given composite standard (e.g. 1)

<section number> is the applicable section number (e.g. 3.1)

For example: HITSP/ISTP-013: 3.1 refers to Section 3.1 in the Interoperability Specification for a Transaction Package, IHE-ITI TF-2: 4.33 refers to Section 4.33 in volume 2 of the IHE IT Infrastructure Technical Framework.

Reproductions

Where large sections of composite standards or base standards are reproduced within a HITSP specification, the reproduced sections are cited with introductory text containing the reference information for the composite or base standard. In addition, the beginning and ending of the reproduced text are respectively shown using a beginning statement:

The text for the <composite or base standard name> specification begins here:

And an ending statement:

The text for the <composite or base standard name> ends here.

2.5 COMMENTS

To submit comments for this interoperability specification, please download the Comment Submission sheet from the HITSP site at www.hitsp.org and provide all relevant information, and then email the completed document to hitspcomments@ansi.org. Comments are consolidated periodically and sent to the Technical Committees for review.

2.6 COPYRIGHT PERMISSIONS

3.0 STANDARDS REFERENCES

The Biosurveillance Technical Committee (Bio TC) has focused its work around an analysis of the Harmonized Biosurveillance Use Case provided by the American Health Information Community (AHIC). This work has also been informed by the proceedings of the AHIC Biosurveillance Workgroup Data Steering Committee (BDSC).

The Biosurveillance TC has selected standards first in accordance with HITSP Tier 1 and Tier 2 processes. The TC worked with USHIK to evaluate the metadata and repository for use in standards selection using demographic and encounter data as a test case. The results and the resource will be used in extension of this interoperability specification to additional domains and clinical data information exchange standards.

This TC has selected standards with more options than might otherwise be defined between communication partners. As Biosurveillance is based upon secondary use of clinical data, the processes and data capture options are somewhat opportunistic, and associated data mining processes have more latitude in translation and data preparation processes. Since it is important to maximize the data sources

to contribute data to the biosurveillance information system, information exchange selections include options for data capture from both legacy environments and emerging environments. Vocabulary, message, and content standards have been selected in consideration of providing the most comprehensive, machine processable fulfillment of the data requirements provided by the AHIC Biosurveillance Data Steering Committee.

3.1 LIST OF BASE STANDARDS

None

3.2 LIST OF COMPOSITE STANDARDS

Composite Standard	Description	Relationships
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF)	Patient Identifier Cross-referencing (PIX) Profile – describes scope and behavior of Patient Identity Source and Patient Identifier Cross-reference Manager	

Table 3.2-1 List of Composite Standards

3.3 LIST OF COMPONENTS

None

4.0 TRANSACTIONS

4.1 CONTEXT OVERVIEW

Pseudonymization: The process of supplying an alternative identifier that permits a patient to be referred to by a key that suppresses his/her actual identification information.

Standard Use Case

In the standard use case, a provider (Patient Identity Source) issues a Patient Identity Feed containing identification and demographic information about a patient to a Patient Identifier Cross-reference (PIX) Manager. PIX Manager registers this patient identity information and invokes a Pseudonymization Service (a trusted third party) to obtain pseudo identifying information to be provided to and used by Patient Identity Consumers, including the originating Patient Identity Source, who inquire about the patient in the context of this provider's domain. The pseudo identifying information provided for this patient in response to this provider's patient identity feed is unique and distinct from the information provided in response to any other provider's feed.

A second provider may issue a Patient Identity Feed to the PIX Manager containing identification and demographic information about the same patient within a different domain. As with the first provider, the PIX Manager will register this information and invoke the Pseudonymization Service to obtain pseudo

identifying information to be provided to and used by Patient Identity Consumers, including the originating Patient Identity Source, who inquire about the patient in the context of this second provider's domain. The pseudo identifying information provided for this patient in response to this second provider's patient identity feed is unique and distinct from the information provided to any other provider's feed, including that of the first provider.

Relationships among Real and Pseudo Identifiers

The PIX Manager maintains associations among all identifiers for a patient, both real identifiers and pseudo identifiers, in all domains. Pseudo identifiers will be provided in response to any Get Patient Identifier request by any domain having a relationship with the PIX Manager. However, note that only the PIX Manager is aware of the relationships among all the "real" identities of the patient. Each provider only knows the "real" identifying information that it assigns and maintains, while the PH agency does not know any "real" identifying information.

Public Health Extension

As an extension of the standard use case given immediately above, a public health agency, as part of documents or transactions sent to it, may receive information about individual patients within its jurisdiction. Prior to the transmission of this information, the Patient Identifier Cross-reference Manager can be directed to invoke the Pseudonymization Service to allot a third set of pseudo-identifying information to be transmitted to the PH agency, suppressing the actual identification of the patient.

The 2006-2007 cycle of HITSP will only address the standard use case.

Pseudonymization through the trusted third party can support re-identification. While re-identification is not required in the current Biosurveillance use case (Populate BIS), use of the information in the context of case investigation and other public health event detection and management will require re-identification capabilities. Reasons for re-identification that should be considered in future specifications include, in accordance with ISO DTS25237:

- verification and validation of data integrity
- checking for suspected duplicate records
- enabling requests for additional data
- linking to supplement research information variables
- compliance audit
- informing data subject or their care provider of significant findings
- facilitate follow-up research
- law enforcement

4.1.1 CONTEXTUAL CONSTRAINTS

Patient Identity Consumers may not receive real identifiers, but only pseudo identifiers, for patient records outside their own domain.

4.1.2 BUSINESS ACTORS

Actor	Description
Pseudonymization Service	Module or service that can be invoked by Patient Identifier Cross-reference Manager (see next section) to return pseudo-identifier upon request

Table 4.1.2-1 List of Business Actors

4.1.3 TECHNICAL ACTORS

Actor	Description
Patient Identity Source	System that maintains a domain patient index including all known identifiers (real and pseudo) for each patient within its domain. Also a Patient Identity Consumer for the purpose of receiving pseudo identifiers for patients within its domain.
Patient Identifier Cross-reference (PIX) Manager	System that maintains a cross-domain patient index including all known identifiers (real and pseudo) for each patient within all domains with which it communicates .
Patient Identity Consumer	System that wishes to know alternate identifiers (real and pseudo) for patients within its domain or pseudo identifiers for patients outside its domain.

Table 4.1.3-1 List of Technical Actors

4.1.4 ACTOR INTERACTIONS

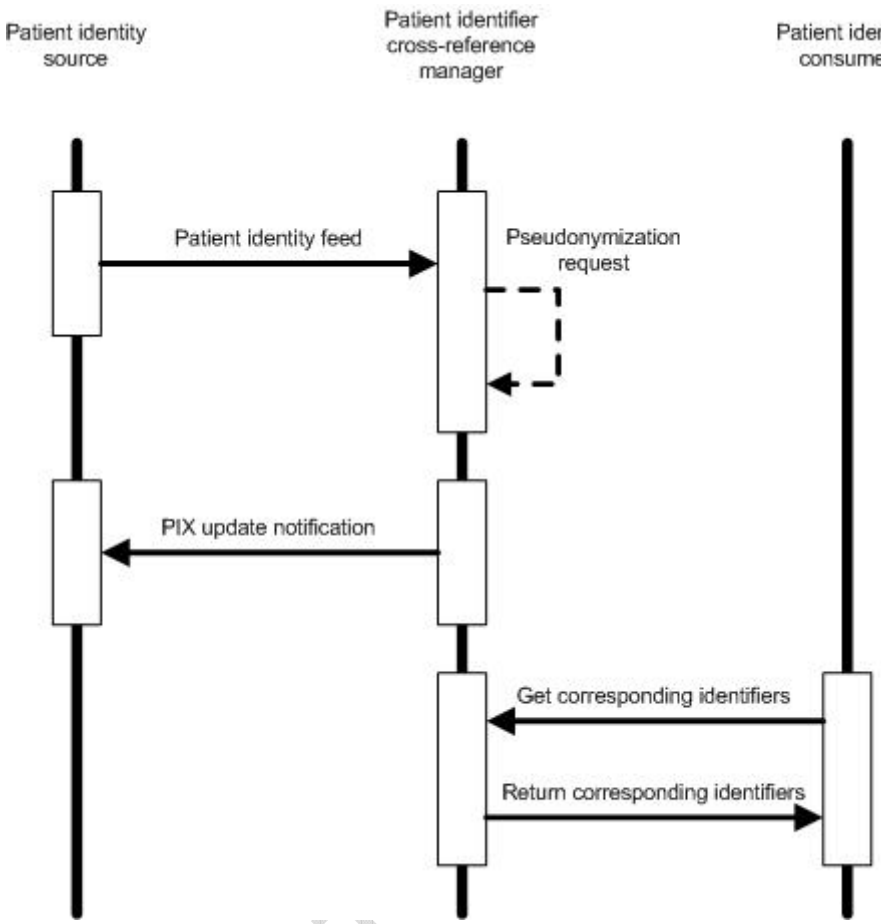

Figure 4.1.4-1 Actor Interactions

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4.2 PROCESS FLOWS

4.2.1 PATIENT IDENTITY FEED

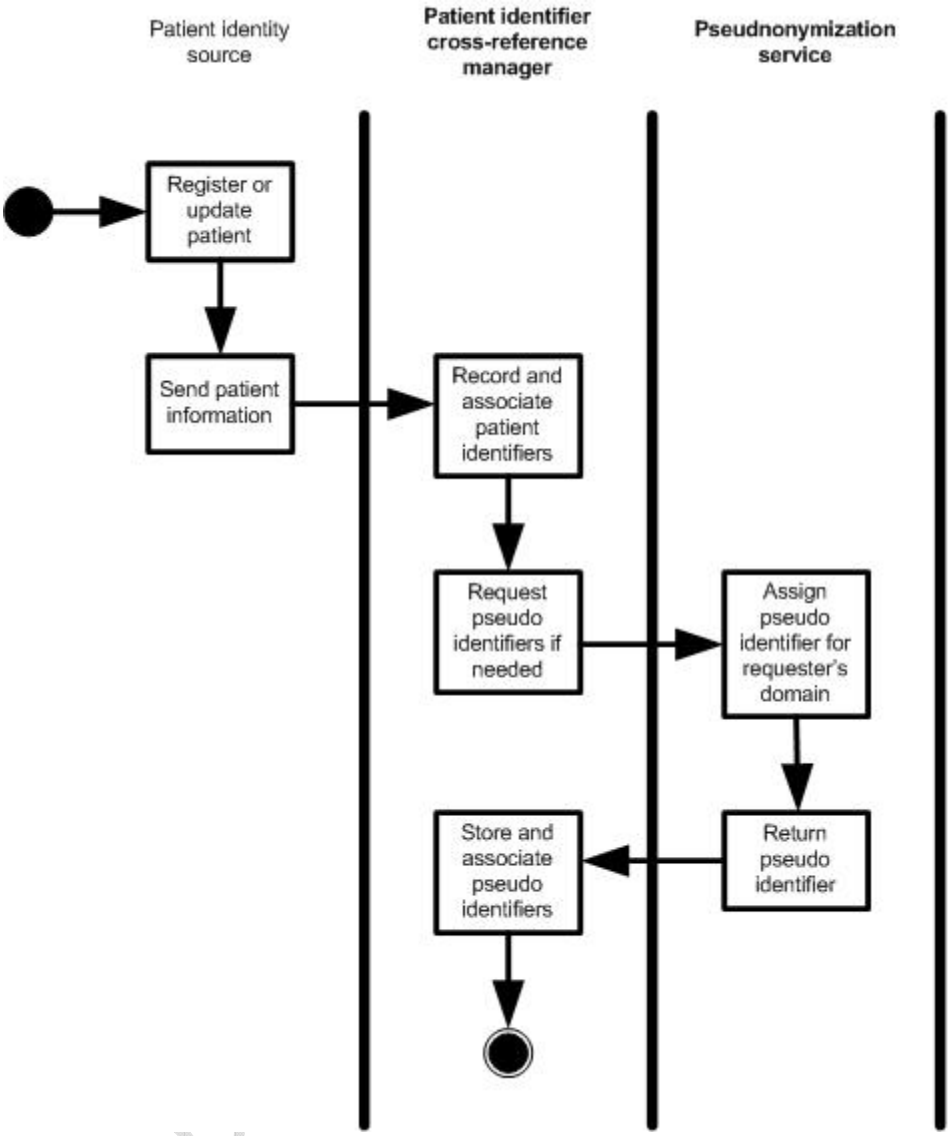

Figure 4.2.1-1 Patient Identity Feed

4.2.2 PIX QUERY

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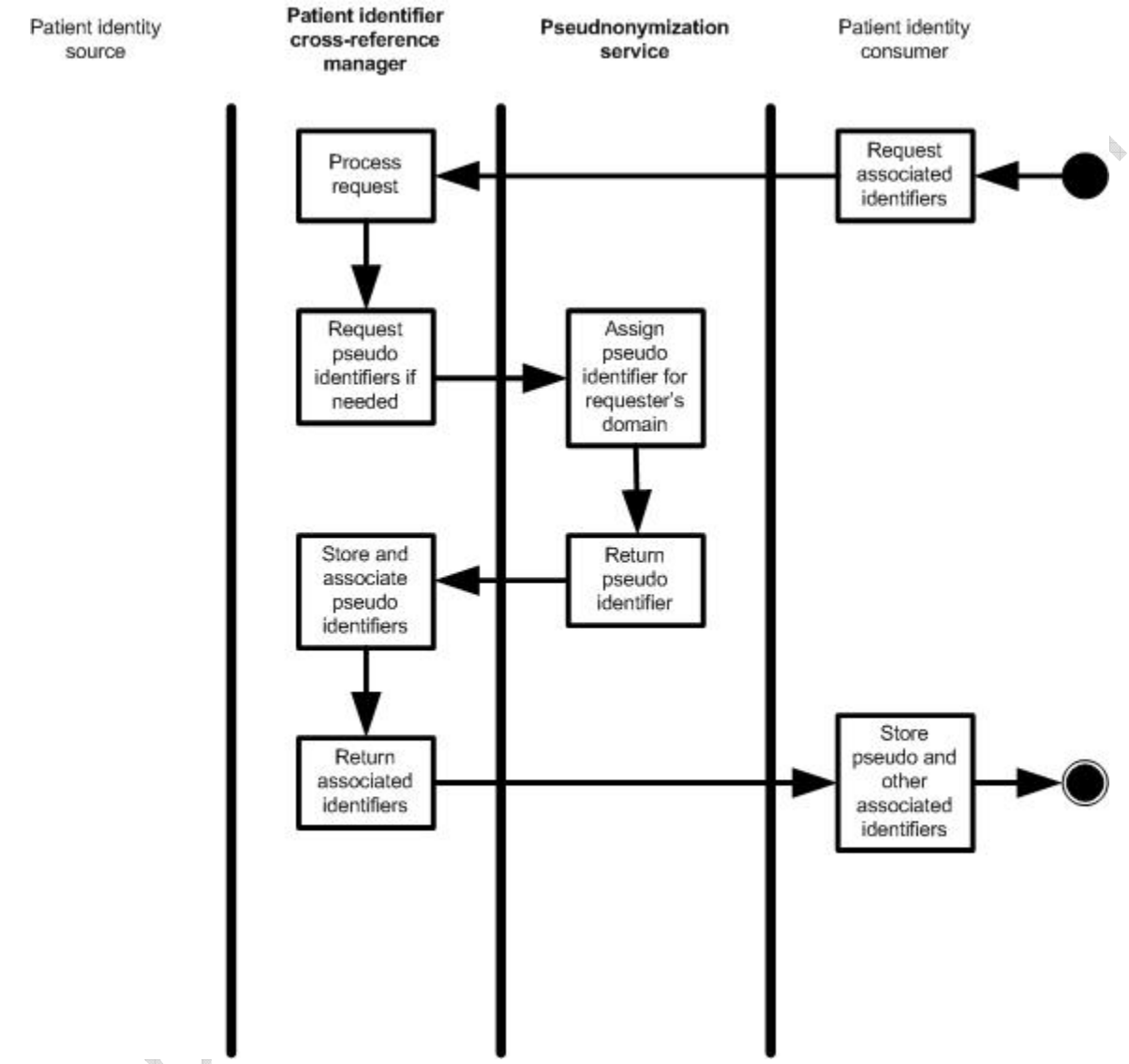

Figure 4.2.2-1 Pix Query

4.2.3 PIX UPDATE NOTIFICATION

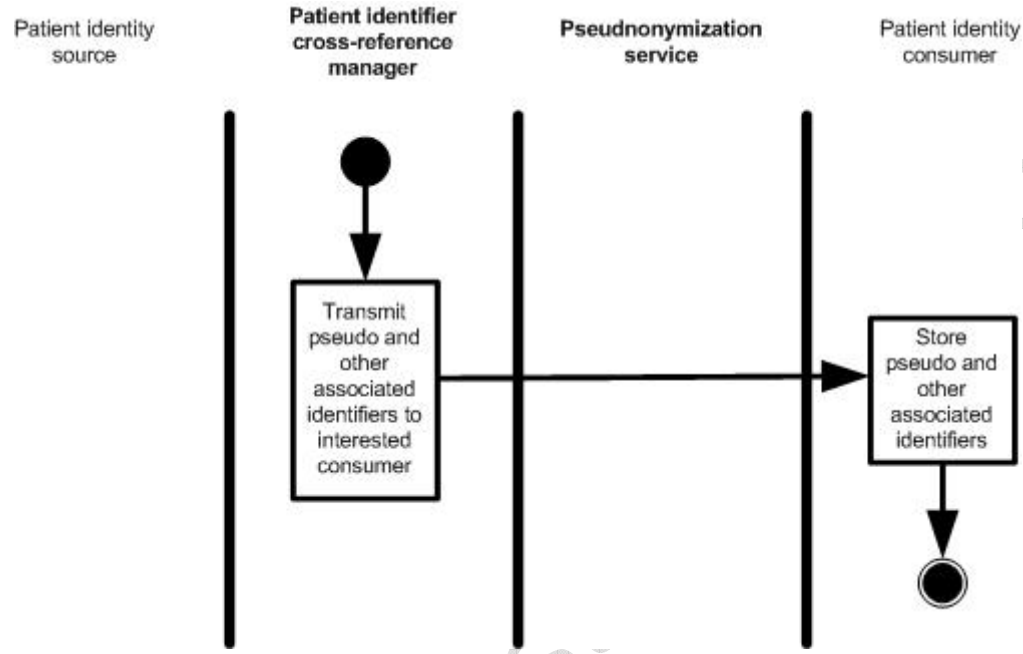

Figure 4.2.3-1 PIX Update

4.2.4 PROCESS PRE-CONDITIONS

Patient Identifier Cross-Reference Manager will have established a relationship of trust with the Pseudonymization Service.

The Patient Identity Source will be known both to the Patient Identifier Cross-Reference Manager and to the Pseudonymization Service.

4.2.5 PROCESS POST-CONDITIONS

Upon request, the Patient Identifier Cross-Reference Manager will provide pseudo identification information to any Patient Identity Consumer with which it has established a relationship of trust. If that Patient Identity Consumer is also a trusted Patient Identity Source, it will also be provided real identifiers in the context of that Patient Identity Source; otherwise (as in the case of a PH agency) it will not be provided any real identifiers.

4.3 DATA FLOWS

The details of the data flows of the Patient Identity Feed, PIX Query, and PIX Update Notification may be found in HITSP/IST-22, *HITSP Interoperability Specification: Patient ID Cross-Referencing (PIX) and Patient Identity Feed Transactions*.

To obtain pseudo identifying information for a patient, Patient Identifier Cross-reference Manager invokes Pseudonymization Service via a remote procedure call (RPC) to which it passes ***patient demographic information*** that is mapped using a cryptographic algorithm by Pseudonymization Service to the pseudo information that is returned to the caller.

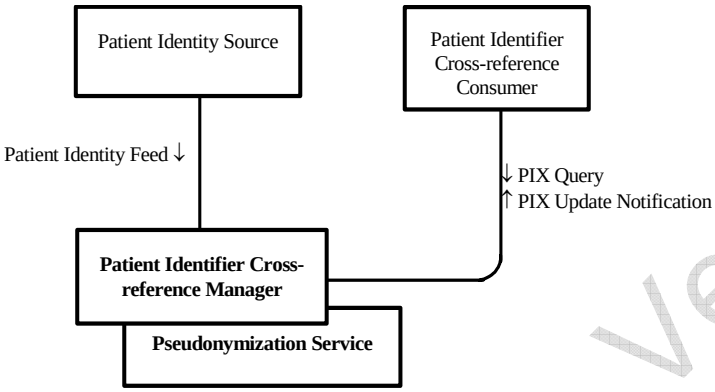

Figure 4.3-1 Obtain pseudo identifying information for patient

5.0 CONSTRAINTS FOR REUSE

Systems may be integrated to allow organizations implementing Patient Demographic Query ("PDQ", HITSP/IST-23) to receive pseudonymized identification information. This is done by binding a PDQ actor to a PIX actor in one of the following groupings:

- PDQ Patient Demographics Supplier with PIX Patient Identifier Cross-reference Manager;
- PDQ Patient Demographics Supplier with PIX Patient Identifier Cross-reference Consumer;
- PDQ Patient Demographics Consumer with PIX Patient Identifier Cross-reference Consumer.

Implementation considerations for each of these groupings are discussed in Appendix M, "Using Patient Demographics Query in a Multi-Domain Environment," of Volume 2 of the IHE IT Infrastructure Technical Framework.

6.0 APPENDIX

6.1 Base Standards Used in IHE-ITI-TF-PIX

To support the use of this transaction instruction, we include the following information for your reference:

Context Standards	
Standard	Description
None	

Information Interchange Standards	
Standard	Description
Health Level 7 v2.5	ADT^A01 – Admit a Patient ADT^A04 – Register an Outpatient
	ADT^A05 – Pre-register a Patient ADT^A08 – Patient Information Update ADT^A40 – Merge Patient Identifier List
Terminology Standards	
Standard	Description
None	
Security Standards	
Standard	Description
ISO/DTS 25237	Health Informatics – Pseudonymization
DICOM Supplement 55	Attribute Level Confidentiality (including De-identification)
Identifier Standards	
Standard	Description
None	
Functionality and Process/Process and Workflow Standards	
Standard	Description
None	
Legislative Standards	
Standard	Description
HIPAA	Reference: NIH Publication Number 003-5388. 'Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule.'
Other Standards	
Standard	Description
None	

Table 3.1-1 List of Base Standards

6.2 GLOSSARY

Included is the common interoperability glossary that is used for all the Use Cases. This is the HITSP glossary that spans all the interoperability specifications, which can be found in the following folder on the HITSP site:

http://publicaa.ansi.org/sites/apdl/Documents/Forms/AllItems.aspx?RootFolder=http%3a%2f%2fpublicaa%2eansi%2eorg%2fsites%2fapdl%2fDocuments%2fStandards%20Activities%2fHealthcare%20Informatics%20Technology%20Standards%20Panel