HITSP Retrieve Form for Data Capture Transaction Package

HITSP/TP50

Submitted to:
Healthcare Information Technology Standards Panel

Submitted by:
Population Health Technical Committee
## Document Change History

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Description of Change</th>
<th>Name of Author</th>
<th>Date Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Ready for Public Comment</td>
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1.0 INTRODUCTION

As an introduction to the HITSP Retrieve Form for Data Capture Transaction Package, this section provides a high level overview of the information sharing scenario enabled by following this specification, provides a document map of the construct relationships for this specification, acknowledges the copyright protections that pertain and provides links to key reference documents and background material. If you are already familiar with this information, proceed to Section 2.0 Transaction Package Definition.

1.1 OVERVIEW

This section describes the contents of this specification and provides a high level definition of this Transaction Package and background information about the underlying Transactions and Components that the Transaction Package is based on.

The Transaction Package enables capture of supplemental data variables not typically maintained in an electronic health record or laboratory information system through a more seamless integration with the local information system. This allows for the local system to retrieve a form specific to the identified potential public health threat. In the context of quality, it allows for the local system to capture supplemental data elements required for quality reporting that may not be available to the electronic health record.

1.2 TRANSACTION PACKAGE DOCUMENT MAP

Each HITSP specification describes a suite of constructs that, taken as a whole, define how to integrate and constrain existing standards and specifications that will satisfy the requirements for the HITSP construct. There are four types of HITSP constructs called Interoperability Specifications (IS), Transaction Packages (TP), Transactions (T) and Components (C). Interoperability Specifications define the context(s) in which any other HITSP construct may be used. The current Retrieve Form for Data Capture Transaction Package specification is used, along with other constructs to meet the requirements of one or more ISs. Review Section 1.2 (Interoperability Specification Document Map) from the relevant IS to better understand the context, dependencies and relationships between the constructs used to meet the IS requirements. The document map in Figure 1.2-1 depicts how this construct integrates and constrains HITSP constructs and existing standards selected or referenced to support the information exchange between two or more systems, within the defined context of this document. Implementers should read the documents that describe the constructs depicted in the diagram for their details and specific uses.
1.3 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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text is not altered in any fashion and ANSI's copyright is clearly noted.

IHE materials used in this document have been extracted from relevant copyrighted materials with
permission of Integrating the Healthcare Enterprise (IHE). Copies of this standard may be retrieved from
the IHE Web Site at www.ihe.net.

1.4 REFERENCE DOCUMENTS

This section contains links to key reference documents and background material.

The HITSP Interoperability Specification Overview provides the background information about the HITSP
and its role in the overall U.S. efforts to realize large scale interoperability of health information. The
document also provides a description of the HITSP process for healthcare standards harmonization and
explains how to use the Interoperability Specifications and other related documents to inform your health
IT product development or product refinement.

The conventions that are used to convey the full descriptions and usage of standards in the HITSP
specifications are contained in the HITSP Conventions List.

The acronyms used in this document are contained in the HITSP Acronyms List.
The HITSP Glossary provides definitions for relevant terms used by HITSP documents.

The HITSP Harmonization Framework describes the current framework within which the Interoperability Specifications are built.

A Technical Note, TN900 - Security and Privacy, has been developed as a reference document to provide the overall context for use of the HITSP Security and Privacy constructs. It includes the following:

- The scope, reference policy background, and Security and Privacy principles used in the development of the constructs
- A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs
- A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases
- A list of identified gaps and the recommended approaches to resolving those gaps
- A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications
- A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment and risk management
- A glossary of terms used in all the Security and Privacy construct documents
- A description of the application of the Security and Privacy constructs to the HITSP Interoperability Specifications for the three initial AHIC Use Cases – Biosurveillance, Electronic Health Records - Laboratory Results Reporting and Consumer Empowerment

HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.
2.0 TRANSACTION PACKAGE DEFINITION

Transaction Packages define how two or more Transactions are used to support a stand-alone information exchange within a defined context between two or more systems.

2.1 CONTEXT OVERVIEW

This section provides a general description of the Transaction Package. It includes a detailed definition of the Transaction Package and the reason for its use. It also provides all the necessary background information that further describes the context in which the Transaction Package is needed, and the independent Transactions and Components that the Transaction Package is based on.

In the context of public health, surveillance of reportable conditions typically includes required reporting to laboratories and healthcare providers of defined conditions and test results, which are defined by state public health authorities to be of interest for the monitoring and management of potential public health threats. These reports include some information available in the clinical or laboratory information systems, but also typically include a number of supplemental information variables specific to the reportable disease that require human input or computation from one or many systems. The Retrieve Form for Data Capture Transaction Package will enable such data capture from within the user's clinical information system which will help to improve the workflow and timeliness of required reporting.

In the context of quality, the patient-level data collected from providers are sent to for analysis and aggregation to compute the quality measures and to generate comparative reports. While the patient-level quality data may be retrieved from the local system, much of the information is often unavailable to the system generating the patient-level quality data. The HITSP Retrieve Form for Data Capture Transaction Package will enable the provider to capture from within the clinical information system that information not available in electronic format through supplemental data entry within the clinical information system.

2.1.1 TRANSACTION PACKAGE CONSTRAINTS

This section describes the constraints that limit the context in which the Transaction Package construct may be used. A constraint describes a rule that limits the use of the actors, actions or data within the given context, or to which the interactions must conform to be used within the described context. It is a description of the limits and scope of the interactions and can describe actions or events that are not part of the initial definition for the context.

<table>
<thead>
<tr>
<th>Constraint</th>
<th>Constraint Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>No applicable constraints</td>
<td></td>
</tr>
</tbody>
</table>
2.1.2 TECHNICAL ACTORS

This section describes the technical actors that need to be integrated in order to meet the interoperability requirements for this Transaction Package. A technical actor represents an entity internal to a software application, which is engaged in one or more specific Transactions to support a specific aspect of a real world information interchange (e.g., set of message exchanges). The table below lists the technical actors involved in the Transaction Package, a definition of their roles, an indication of their optionality, the specific Transactions and content with which they are involved and the optionality of the associated Transactions and/or content.

<table>
<thead>
<tr>
<th>Actor</th>
<th>Description</th>
<th>Used in Component/Standard</th>
<th>Transaction/Content</th>
<th>Optionality*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form Filler</td>
<td>The actor responsible for retrieving a form from a Form Manager and for submitting form instance data to a Form Receiver. The mechanism by which a unique identification of a form is obtained is outside the scope of the Retrieve Form for Data Capture profile</td>
<td>HITSP/TP50</td>
<td>Retrieve form</td>
<td>R</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Submit form</td>
<td>R</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Archive form</td>
<td>O</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Retrieve clarifications</td>
<td>O</td>
</tr>
<tr>
<td>Form Manager (Option for CIS supporting form management locally)</td>
<td>The actor that supplies a form based upon a request that supplies unique form identification</td>
<td>HITSP/TP50</td>
<td>Retrieve form</td>
<td>R</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Retrieve clarifications</td>
<td>R</td>
</tr>
<tr>
<td>Form Receiver (Option for CIS supporting form management locally)</td>
<td>The actor that receives form instance data</td>
<td>HITSP/TP50</td>
<td>Submit form</td>
<td>R</td>
</tr>
<tr>
<td>Form Archiver (Option for CIS supporting form management locally)</td>
<td>The actor responsible for receiving form instance data for archival purposes</td>
<td>HITSP/TP50</td>
<td>Archive form</td>
<td>R</td>
</tr>
</tbody>
</table>

*NOTE: Optionality = “R” for Required, “R2” for Required if known, “O” for Optional or “C” for Conditional. If applicable, conditional footnotes are further described below.

2.1.3 ACTOR INTERACTIONS

This section uses a Unified Modeling Language (UML) workflow diagram to depict the business and technical actors, the relevant events or actions in which they are involved and a mapping to the Transactions and Components that encapsulate the defined events/actions. It describes the underlying events that fulfill the Transaction Package, the sequence and timing of the events and the specific actors involved. Process flow diagrams are also provided to illustrate the process relationships. A description of the UML diagram is also provided below the diagram.
2.1.4 PRE-CONDITIONS

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

**Table 2.1.4-1 Pre-conditions**

<table>
<thead>
<tr>
<th>Pre-condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is expected that the security framework under which this Transaction Package operates is in accordance with the Interoperability Specification that references this construct. Therefore all applicable HITSP Security and Privacy constructs are implemented as required.</td>
</tr>
<tr>
<td>For Biosurveillance, state public health authorities have defined supplemental data forms to capture data values of interest for management and monitoring of reportable conditions.</td>
</tr>
<tr>
<td>These data forms have been expressed in XFORMS (not specified by this Transaction Package– rather this is left to the discretion of the implementer).</td>
</tr>
<tr>
<td>For Biosurveillance, a reportable condition or laboratory value is generated in the Clinical Information System or Laboratory Information System.</td>
</tr>
</tbody>
</table>

2.1.4.1 Process Triggers

This section describes the triggers, including actors and/or processes, which are necessary to start the Transaction Package. They can invoke an automatic or manual process or result that in turn initiates the
Transaction Package. A trigger is not the same as a pre-condition that describes a context that needs to be in place at the start of the event.

### Table 2.1.4.1-1 Process Triggers

<table>
<thead>
<tr>
<th>Process Trigger</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triggers would be specific to the implementation</td>
</tr>
</tbody>
</table>

#### 2.1.5 POST-CONDITIONS

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

### Table 2.1.5-1 Post-conditions

<table>
<thead>
<tr>
<th>Post-condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data captured by the form is successfully transmitted to the public health authority or other business actor implementing the form receiver technical actor</td>
</tr>
</tbody>
</table>

#### 2.1.5.1 Required Outputs

This section identifies the required outputs that must be produced at the end of the Transaction Package in order for the Transaction Package to be deemed successfully completed. This includes the format and usage of the required output.

### Table 2.1.5.1-1 Required Outputs

<table>
<thead>
<tr>
<th>Required Output</th>
<th>Format/Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No applicable required outputs</td>
<td></td>
</tr>
</tbody>
</table>

#### 2.1.6 DATA FLOWS

This section describes the basic data flows that are supported by this Transaction Package. It also describes the format of the data, the data sources and the relevant actors involved in the successful flow of data for the Transaction Package. Any prevailing pre and post-conditions are identified, as well as the purpose of each data post-condition associated with each Transaction Package. Any data that need to be made available to particular actors are highlighted, as well as the conditions and processes that will use the data to achieve the stated post-conditions.

All data flows associated for this Transaction Package are specified in Section 17.4 of the IHE IT Infrastructure Technical Framework Retrieve Form for Data Capture Integration Profile.
2.2 LIST OF CONSTRUCTS

The following list of constructs and their definitions are used by the Transaction Package specification.

Table 2.2-1 List of Constructs

<table>
<thead>
<tr>
<th>Construct Name</th>
<th>Technical Actor</th>
<th>Description</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>No applicable constructs</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2.2.1 CONSTRUCT DEPENDENCIES

The following table shows a list of constructs with their existing dependencies. Dependencies usually exist when there are some additional pre-requisites for a specific Transaction Package specification.

Table 2.2.1-1 Construct Dependencies

<table>
<thead>
<tr>
<th>Construct</th>
<th>Depends On</th>
<th>Dependency Type</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrieve Form, Archive Form, Submit Form</td>
<td>IHE ITI:19 Authenticate Node</td>
<td>General</td>
<td>Security Risk Mitigation</td>
</tr>
</tbody>
</table>

2.2.2 ADDITIONAL CONSTRAINTS ON REQUIRED CONSTRUCTS

This section describes the constraints that further limit the constructs that are used by this Transaction Package.

Table 2.2.2-1 Additional Constraints on Required Constructs

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Construct</th>
<th>Constraint</th>
<th>Constraint Type</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>No applicable constraints</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2.3 LIST OF STANDARDS

It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts. The following standards are used to implement the Transaction Package specification:
Table 2.3-1 List of Standards

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical</td>
<td>The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 3.0 for Final Text, specifies the IHE transactions defined and implemented as of December 9, 2006. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>.</td>
</tr>
<tr>
<td>Framework (ITI-TF) Revision 3.0</td>
<td></td>
</tr>
<tr>
<td>Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical</td>
<td>Supplement (ITI TF-Supplement) Retrieve Form for Data Capture (RFD), IHE TF</td>
</tr>
</tbody>
</table>
3.0 TECHNICAL IMPLEMENTATION

3.1 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface or code set has been implemented correctly.

3.1.1 CONFORMANCE CRITERIA

In order to claim conformance to this construct specification, an implementation must satisfy all the requirements and mandatory statements listed in this specification, the associated HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also be constrained as specified in Table 2.1.1-1 and implement all of the required actors from Table 2.1.2-1 within the scope, subset or implementation option that is selected from the associated Interoperability Specification.

Claims of conformance may only be made for the overall HITSP Interoperability Specification with which this construct is associated.

3.1.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification must be implemented in its entirety for an implementation to claim conformance to the specification. HITSP may define the permissibility for actor scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. Such scoping, subsetting and options may extend to associated constructs, such as this construct. This construct must implement all requirements within the selected scope, subset or options as defined in the associated Interoperability Specification to claim conformance.
4.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

No additional information at this time.
5.0 CHANGE HISTORY

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

5.1 DECEMBER 13, 2007

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

5.2 MARCH 19, 2008

The following changes have been made to the construct:
- Updated overview language to generalize the use to extend beyond public health
- Added process trigger statement
- Updated Figures 1.2-1 and 2.1.3-1

5.3 MARCH 27, 2008

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