Integrating the Healthcare Enterprise



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IHE Dental Technical Framework Supplement

Secure Exchange of Dental Information (SEDI)

Trial Implementation

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Foreword

This is a supplement to the forthcoming IHE Dental Technical Framework. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on September 06, 2013 for Trial Implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into Dental Technical Framework. Comments are invited and may be submitted at http://www.ihe.net/Dental Public Comments.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **bold strikethrough**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at: www.ihe.net.

Information about the IHE Dental domain can be found at: http://www.ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: http://www.ihe.net/IHE_Process and http://www.ihe.net/Profiles.

The current version of the IHE Dental Technical Framework can be found at: http://www.ihe.net/Technical_Frameworks.

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Introduction to this Supplement

Secure Exchange of Dental Information (SEDI) is a content profile for the transmission of dental documents and objects using a point-to-point reliable web system specified by Cross-Enterprise Document Reliable Interchange (XDR) and to optionally exchange the documents and objects via email specified in Cross-Enterprise Document Media Interchange (XDM). This permits the direct interchange between image-capable healthcare systems.

Open Issues and Questions

125 N/A

Closed Issues

| # | Issue/ (Answer) | | |
|----|---|--|--|
| 1. | The Radiology profile does not allow for ZIP to be used for DICOM files. The reason for their choice is as follows: | | |
| | It is not necessary. DICOM images already have the capability for full lossless and lossy compression with DICOM formats. Most PACS already have the capability to compress/uncompress with DICOM. There is no advantage that I can see using zip on top of that. It won't get any better compression. Plus the DICOM attributes are readable and the images are manageable without requiring uncompressing of the blob first. | | |
| | Decision: It was decided to include support for ZIP. The main reason is that since it is already part of the DICOM e- mail transport specification it will be used and it is more convenient to just send the zip DICOM email files when using XDR. Also it is not seen as a burden to support as ZIP is widely used in most platforms as dental implementations do not have as much implementation experience with other compression algorithms. | | |
| 2. | What about inconsistent patient identifiers? How is the receiving site going to know how to match the incoming images that use the imaging center's patient identifier against their own internal patient identifier. | | |
| | Decision: Importing is beyond the scope of this profile. Implementations may wish to use the IHE Import Reconciliation Workflow (IRWF) profile. | | |
| 3. | For the DICOM Email Transport transaction, DICOM WG22 in the DICOM standard chose ZIP. But there are a number of file based compression and encryption algorithms that will work well with DICOM files: ZIP, JPEG2000, NIST FIPS 140-2 | | |
| | Why limit the algorithm choice? | | |
| | Decision: Compression beyond ZIP is not widely supported in the dental domain. Decided that all systems are required to support sending the data uncompressed or using ZIP only. Other lossless compression is optional (lossy is not supported by this profile), but systems must be able to send the files uncompressed. This is also true for web transmissions. | | |

| # | Issue/ (Answer) | | |
|----|--|--|--|
| 4. | The current IHE Portable Data for Imaging (PDI) profile doesn't support compression. This profile does specify PDI but may be useful for implementations. Since we wish to support compression it would be incompatible. | | |
| | Decision: See PDI Extensions for more information. We are not addressing PDI with this profile. IHE Dental may work with Radiology to ask for compression support in the future. | | |
| 5. | Do we want the ability to turn off compression and encryption – i.e., the use case of forwarding images to a patient? | | |
| | Decision: Yes, this is discussed in open item 3. | | |
| 6. | Should we include the "For_Processing" Image Storage SOP Classes in our list of Dental Related SOP Classes, (i.e., Digital Intra-oral X-ray Image Storage – For Processing)? | | |
| | Decision: The ingoing position is to delete as we believe these SOP Classes are not being used as the "For_Presentation" is what is commonly implemented. Consistent with the DICOM Dental Application Profile for Secure email Transport. | | |
| 7. | In the future, we may look into adding additional DICOM SOP classes to table 7.1.5.1-1. | | |
| 8. | In the future, we may look into revising table 7.1.4.1.1-1. One current priority is to maintain consistency with existing ITI. | | |
| 9. | Currently, there is no dental specific HL7 CDA content that SEDI can specify. All references to CDA in SEDI are based on a future dental specific content being developed for future exchange by the ADA and HL7. Existing non-dental specific structured documents such as an ambulatory summary can be used in a dental setting. | | |

General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A - Actor Summary Definitions

Add the following actors to the IHE Technical Frameworks General Introduction list of Actors:

| Actor | Definition |
|---------------------------|---|
| Dental Document Source | Sends DICOM SOP Instances and image reports and associated documents |
| Dental Document Recipient | Receives DICOM SOP Instances and image reports and associated documents |

Appendix B - Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

None

Glossary

140 None

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Volume 1 – Profiles

Copyright Licenses

NA

145 **Domain-specific additions**

2.3 Integration Profiles Overview

Add the following to the IHE Technical Frameworks Integration Profiles Overview section:

2.3.1 Secure Exchange of Dental Information (SEDI)

The Secure Exchange of Dental Information (SEDI) Content Profile provides DICOM SOP

Instances and image related documents using a reliable web service. It also allows for the option to support email transport of these imaging documents. SEDI permits direct imaging document interchange between a Dental Document Source and other healthcare IT imaging document-capable systems.

This profile depends on the IHE IT Infrastructure Cross-Enterprise Document Reliable Interchange (XDR) profile for reliable messaging. For the email option, this profile depends on the Cross-Enterprise Document Media Interchange (XDM) profile.

This profile addresses data content specific to Dental. Content includes sets of DICOM instances (including dental images, evidence documents, and presentation states, encapsulated PDFs) and dental based documents provided in a ready-for-display format.

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Add Section 3.0

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3 Secure Exchange of Dental Information (SEDI) Profile

- The Secure Exchange of Dental Information (SEDI) Content Profile provides the secure exchange of DICOM SOP Instances and image related documents using a reliable web based messaging service. It also allows for the option to support email transport of these imaging documents. SEDI permits direct imaging document interchange between a Dental Document Source and other healthcare IT imaging document-capable systems.
- This profile depends on the IHE IT Infrastructure Cross-Enterprise Document Reliable

 Interchange (XDR) profile for reliable messaging. For the email option, this profile depends on the Cross-Enterprise Document Media Interchange (XDM) profile.
 - This profile addresses data content specific to Dental. Content includes sets of DICOM instances (including dental images, evidence documents, presentation states, and encapsulated PDFs) and dental image based documents provided in a ready-for-display format.
- In order to support web exchange SEDI depends on XDR and uses the ITI-41 Provide and Register Document Set-b transaction, with MTOM/XOP as transport. Transfer is direct from source to recipient. The XDS Metadata, with emphasis on patient identification, document identification, description, and relationships, is leveraged by this profile.
- In order to support email exchange SEDI depends on XDM ZIP email option and uses the IHE Distribute Document Set on Media [ITI-32] transaction with the ZIP over Email and ZIP over Email Response options.

SEDI is intended to support images and documents, specifically including the following:

- Images acquired on various modalities, as well as evidence documents (e.g., post-processing measurements/analysis outcomes), and presentation states.
- Dental documents, resulting from the interpretation of one or more imaging studies, provided in a ready-for-display form (such as PDF, DICOM encapsulated PDF)
- Text data only or XML coded data
- Documents formatted with data using the HL7 CDA V2 format
- These document types along with the actor capabilities required to share them are defined by this profile.

3.1 SEDI Actors, Transactions and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://www.ihe.net/Technical_Framework/index.cfm.

Figure 3.1-1 shows the actors directly involved in the SEDI Profile and the direction that the content is exchanged. SEDI is a content profile for XDR and XDM.

A product implementation using this profile must group actors from this profile with actors from a workflow or transport profile to be functional. The grouping of the content module described in this profile to specific actors is described in more detail in the "Required Actor Groupings" section below.

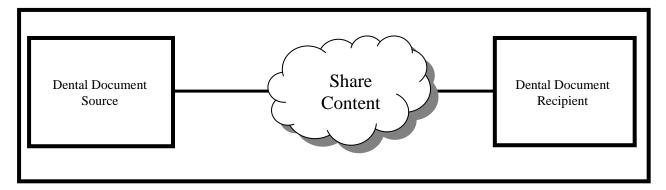


Figure 3.1-1: SEDI Actor Diagram

The two actors in the SEDI profile are Dental Document Source and Dental Document Recipient. A Dental Document Source Actor is the source for images, documents or other related DICOM objects. A Dental Document Recipient Actor receives images, documents or other related DICOM objects. The sharing or transmission of the content from one actor to another is addressed by the appropriate use of the XDR profile described in the section on Content Bindings for SEDI in DENT TF-3: 7.1.3.

These types of content are transported as SEDI Document Objects:

- Images acquired on various modalities, as well as evidence documents (e.g., post-processing measurements/analysis outcomes), presentation states and DICOM encapsulated PDF.
 - Dental documents, resulting from the interpretation of images and evidence documents, provided in a PDF ready-for-display form
- Text data only or XML coded data
 - Documents formatted with data using the HL7 CDA V2 format

Document Types

The SEDI Document types permitted by this profile are listed in Table 3.1-2. See the referenced Volume & Section for a specification of each document type.

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Table 3.1-1: SEDI – Document Types

| Imaging Document Type | Volume & Section | |
|-------------------------------|--------------------|--|
| Sharing of DICOM SOP Instance | DENT TF 3: 7.1.5.1 | |
| Sharing of PDF Report | DENT TF 3: 7.1.5.2 | |

| Imaging Document Type | Volume & Section | |
|------------------------|--------------------|--|
| Sharing of text or XML | DENT TF 3: 7.1.5.3 | |
| Sharing of CDA | DENT TF 3: 7.1.5.4 | |

3.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirements on profile's actors.

225 3.1.1.1 Dental Document Source

In order to support web exchange, the Dental Document Source utilizes the ITI XDR Document Source. SEDI utilizes the ITI XDR profile and uses the ITI-41 Provide and Register Document Set-b transaction, with MTOM/XOP as transport. Web transfer is direct from source to recipient.

- The SEDI dental document source actor provides metadata that is associated with a document.

 SEDI generally utilizes XDS Metadata, with emphasis on patient identification, document identification, description, and relationships, is leveraged by this profile. SEDI Content Modules describes the metadata that must be provided with this dental document, and describes where this metadata can be obtained.
- The Content Modules define the source for all required attributes and optional attributes for dental uses. The Content Modules describe the three main XDS object types: XDSDocumentEntry, XDSSubmissionSet, and XDSFolder. XDSSubmissionSet and XDSDocumentEntry are required. Use of XDSFolder is optional.
- In order to support the optional email exchange, the Dental Document Source utilizes the XDM Portable Media Creator. SEDI depends on the XDM ZIP email option and uses the IHE Distribute Document Set on Media [ITI-32] transaction with the ZIP over Email and ZIP over Email Response options.

3.1.1.2 Dental Document Recipient

In order to support web exchange, the Dental Document Recipient utilizes the ITI XDR Document Recipient. SEDI utilizes the ITI XDR profile and uses the ITI-41 Provide and Register Document Set-b transaction, with MTOM/XOP as transport. Web transfer is direct from source to recipient. The XDS Metadata, with emphasis on patient identification, document identification, description, and relationships, is leveraged by this profile.

In order to support the optional email exchange, the Dental Document Recipient utilizes XDM Portable Media Importer. SEDI depends on XDM ZIP email option and uses the IHE Distribute Document Set on Media [ITI-32] transaction with the ZIP over Email and ZIP over Email Response options.

3.2 SEDI Actor Options

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The Dental Document Source and Recipient shall support the exchange requirements specified below. Options that may be selected for each actor in this profile, if any, are listed in the table 3.2-1. Dependencies between options when applicable are specified in notes.

Table 3.2-1: SEDI - Actors and Options

| Actor | Option Name | Reference |
|---------------------------|--|------------------|
| Dental Document Source | Sharing of DICOM SOP Instance (Note 1) | DENT TF-1:3.2.1 |
| | Sharing of PDF Report (Note 1) | DENT TF-1:3.2.2 |
| | Sharing of text or XML (Note 1) | DENT TF-1:3.2.3 |
| | Sharing of CDA | DENT TF-1:3.2.4 |
| | Dental Exchange via Email | DENT TF-1:3.2.5 |
| Dental Document Recipient | Sharing of DICOM SOP Instance (Note 1) | DENT TF-3: 3.2.1 |
| | Sharing of PDF Report (Note 1) | DENT TF-3: 3.2.2 |
| | Sharing of text or XML (Note 1) | DENT TF-3: 3.2.3 |
| | Sharing of CDA | DENT TF-3: 3.2.4 |
| | Dental Exchange via Email | DENT TF-1:3.2.5 |

Note 1: These options are document types. The Dental Document Source and Dental Document Recipient shall support at least one of these options.

260 3.2.1 Sharing of DICOM SOP Instance

This option requires the Dental Document Source Actor to share DICOM SOP Instances with a Dental Document Recipient. For the content specification details of the Sharing of DICOM SOP Instances, refer to DENT TF-3: 7.1.5.1.

3.2.2 Sharing of PDF Report Option

This option requires the Dental Document Source Actor to share an Imaging document in a PDF format with a Dental Document Recipient Actor. The PDF report may contain embedded images that reference images in a non-DICOM format. For the content specification details of the Sharing of PDF Reports, refer to DENT TF-3: 7.1.5.2.

3.2.3 Sharing of text or XML Option

This option requires the Dental Document Source Actor to share XML data stored in plain text format with a Dental Document Recipient Actor.

3.2.4 Sharing of CDA Option

This option requires the Dental Document Source Actor to share an HL7 CDA document coded format with a Dental Document Recipient Actor. Existing non-dental specific structured

documents such as an ambulatory summary can be used in a dental setting. Specific dental content will be developed in the future.

3.2.5 Dental Exchange via Email Option

A Dental Document Source Actor that supports this option shall be grouped with an XDM Portable Media Creator supporting both the ZIP over Email and ZIP over Email Response options. The contents of METADATA.XML as defined in ITI TF-2b:3.32.4.1.2.2 are modified. The Dental Document Source Actor shall support those in DENT TF-3:7.1.4 (rather than .ITI TF-3:4.2.3.2).

The Dental Document Recipient that supports this option shall be grouped with an XDM Portable Media Importer supporting both the ZIP over Email and ZIP over Email Response options. The contents of METADATA.XML as defined in ITI TF-2b:3.32.4.1.2.2 are modified: The Dental Document Recipient Actor shall support those in DENT TF-3:7.1.4 (rather than .ITI TF-3:4.2.3.2).

3.3 SEDI Required Actor Groupings

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An Actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile in addition to all of the transactions required for the grouped actor (Column 2).

If this is a content profile, and actors from this profile are grouped with actors from a workflow or transport profile, the Content Bindings reference column references any specifications for mapping data from the content module into data elements from the workflow or transport transactions.

In some cases, required groupings are defined as at least one of an enumerated set of possible actors; this is designated by merging column one into a single cell spanning multiple potential grouped actors. Notes are used to highlight this situation.

Section 3.5 describes some optional groupings that may be of interest for security considerations.

Table 3.3-1: SEDI - Required Actor Groupings

| SEDI Profile Actor | Actor to be grouped with | Reference | Content Bindings Reference |
|------------------------|--|---------------|-------------------------------|
| Dental Document Source | XDR Document Source | ITI TF-1:15 | |
| | SEDI Dental Document Recipient | DENT TF-1:3.2 | |
| | ATNA Secure Node or Secure Application | ITI TF-1:9 | |
| | CT Time Client | ITI TF-1:7 | |

| SEDI Profile Actor | Actor to be grouped with | Reference | Content Bindings Reference |
|---|--|-----------------|-------------------------------|
| Dental Document Source supporting the Dental Exchange via Email option | XDM Portable Media Creator | DENT TF-1:3.2.4 | |
| Dental Document Recipient | XDR Document Recipient | ITI TF-1: 15.1 | |
| | SEDI Dental Document Source | DENT TF-1:3.2 | |
| | ATNA Secure Node or Secure Application | ITI TF-1:9 | |
| | CT Time Client | ITI TF-1:7 | |
| Dental Document Recipient supporting the Dental Exchange via Email option | XDM Portable Media Importer | DENT TF-1:3.2.4 | |

3.4 SEDI Overview

SEDI describes the exchange of a set of a patient's imaging documents between healthcare providers, such as: providers, dental specialists, dental groups, physicians, hospitals, special care networks, and/or other healthcare professionals. SEDI profile uses web services for the point-to-point transfer of DICOM SOP Instances and image based documents.

3.4.1 Concepts

NA

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3.4.2 Use Cases

310 3.4.2.1 Dental Use Case Point-to-Point Exchange

The following SEDI use cases are typical examples of how SEDI web transactions may be used in a dental scenario. The purpose of these use cases is to identify the user systems used in various dental settings.

3.4.2.1.1 Point-to-Point Web Exchange Use Case Description

- Two dental providers need to exchange imaging objects in a secure and reliable point-to-point web services messaging protocol. Examples (but not limited to) include the following:
 - A dental provider sends diagnostic images and documents to a large dental management facility from outside of the facility's secure network.
 - A dental provider sends diagnostic images and documents to a specialist (i.e., orthodontist, endodontist, periodontist, etc.).

- A dental specialist sends diagnostic images and imaging based documents to the provider.
- Dental group practices include both general dentists and specialists who share images may have various different types of systems.
- 325 The shared imaging objects and metadata content are provided using a direct exchange between the sending and receiving entities. SEDI requires that a Dental Document Source be grouped with a Dental Document Recipient as shown in Table 3.3-1.
- Figure 3.4.2.1.1-1 is an illustration of the workflow for exchanging dental images and documents between a provider and dental specialist. It shows how a practice and its system both transmits and receives dental documents as peers networked to each other. In this workflow, each provider has equivalent capabilities and responsibilities.

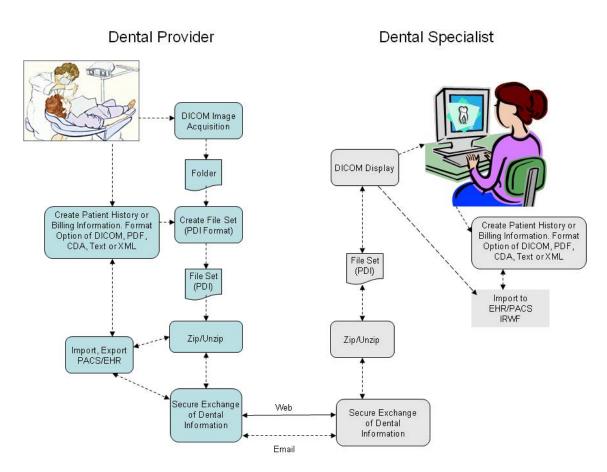


Figure 3.4.2.1.1-1: Exchange of Dental Images and Documents Workflow Example

A patient has an examination at the provider's dental office. It is determined that a set of dental images is needed. The patient/study identifiers are entered into the image acquisition system and the appropriate DICOM images are acquired. The images are typically stored locally (in the DICOM file format).

Upon review of the images the provider decides to order a consultation with a dental specialist (i.e., orthodontist, endodontist, periodontist, etc.). A DICOM image File-Set is created along with an additional file named DICOMDIR containing the manifest and indexing information.

The SEDI metadata allows for the seamless routing and management of documents including, DICOM SOP Instances and reports. The SEDI metadata includes numerous different codes that are associated with the document it indexes. This includes information on the event, the dental practice setting, the document author (i.e., the provider), the specialty and the format provided.

The documents are transmitted to the specialist via web message services. The specialist receives 345 the images/documents and locally views and/or stores the information.

The specialist reviews the received images and documents, creates a new report and transmits this report back to the provider using the web message services.

3.4.2.1.2 "Point-to-Point Exchange" Process Flow

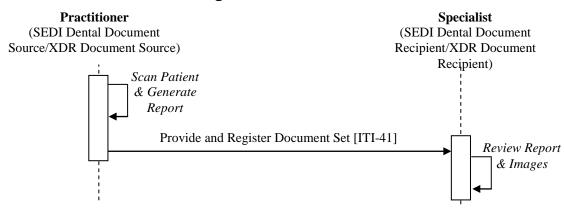


Figure 3.4.2.1.2-1: Point-to-Point Exchange Process Flow

3.4.2.2 Point-to-Point Dental Exchange over Email Option Use Case

The following SEDI use cases are typical examples of how SEDI email transactions may be used in a dental scenario. The purpose of these use cases is to identify the user systems used in various dental settings where email is the preferred option.

3.4.2.2.1 Point-to-Point Dental Exchange over Email Option Use Case Description

Two dental providers need to exchange imaging objects in a secure and reliable point-to-point email messaging protocol. Examples (but not limited to) include the following:

- A provider office provides diagnostic images to a large dental management facility from outside of the facility's secure network.
- A provider office provides diagnostic images to a specialist (i.e., orthodontist, endodontist, periodontist, etc.).
- A specialist office provides diagnostic images and imaging based documents to the provider.

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• Dental group practices include both general dentists and specialists who share images but have various different types of systems.

The use case and workflow is the same as shown in Figure 3.4.2.1.1-1 with the exception that the transmission of the images utilizes email services instead of web messaging. See Figure 3.4.2.1.1-1 and its associated text for the use case workflow description.

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3.4.2.2.2 "Point-to-Point Exchange" Process Flow

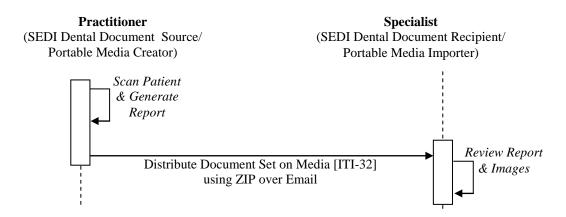


Figure 3.4.2.2.1: Point-to-Point Exchange Process Flow

375 3.5 SEDI Security Considerations

Basic Patient Privacy Consents (BPPC) provides a mechanism to record the patient privacy consent(s) and a method for Content Consumers to use to enforce the privacy consent appropriate to the use. BPPC complements SEDI.

SEDI assumes that the health organizations using the Dental Document Source and Dental

Document Recipient have an agreement defining when they can interchange PHI. This may require an explicit patient consent (depending on the local regulations) and an agreement on how to manage the potential inconsistency between the security policies. The main aspects that should be covered by this agreement are similar to XDS (see ITI TF-1: Appendix L).

3.6 SEDI Cross Profile Considerations

385 NA

Appendices

None

Volume 2 – Transactions

No transactions to add to Volume 2.

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Volume 2 Namespace Additions

Add the following terms to the IHE General Introduction Appendix G:

None

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Bellium Feelman Framework Supplement Secure Exchange of Bellium Information (SEBF)

Volume 3 – Content Modules

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5 Namespaces and Vocabularies

Add to section 5 Namespaces and Vocabularies

400 NA

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6 Content Modules - CDA

The Dental Community is in the process of defining content modules. In the future, this may be updated.

7 Content Modules

This section describes the IHE Content Specifications for Dental.

7.1 SEDI Dental Document Set

7.1.1 Scope

The SEDI Dental Document Set is an IHE Dental Content Specification for the sharing of Dental Document Objects using the ITI Integration Profile, Cross Document Reliable Interchange (XDR).

Additionally, the SEDI profile includes the option to share the Dental Document objects using the ITI Integration Profile, Cross Document Media Interchange (XDM) including the ZIP over Email and ZIP over Email Response options.

The Dental Document Set is a set of SEDI Dental Documents Objects related to an individual patient. This may include imaging documents related to the patient.

An SEDI Dental Document Object is defined as one of the following document types:

- Images acquired on various modalities, as well as evidence documents (e.g., post-processing measurements/analysis outcomes), presentation states and DICOM encapsulated PDF.
- Dental documents, resulting from the interpretation of images and evidence documents, provided in a PDF ready-for-display form.
 - Text data only or XML coded data
 - Documents formatted with data using the HL7 CDA V2 format)
- The Imaging Document Set is submitted as part of a Submission Set using the XDR or the XDM email transport. Refer to ITI TF-1: 10.4.4 for the definition of a Submission Set.

7.1.2 Referenced Standards

DICOM PS 3.3 Information Object Definitions

DICOM PS 3.10 Media Storage and File Format for Media Interchange

PDF/A ISO 19005-1. Document management - Electronic document file format for long-term preservation - Part 1: Use of PDF (PDF/A)

HL7 CDA Release 2.0 (denoted HL7 CDA R2, or just CDA, in subsequent text)

For a list of other standards inherited from the underlying ITI-41 Provide and Register Document Set-b, see ITI TF-2b: 3.41.3.

For a list of other standards inherited from the underlying ITI-32 Distribute Document Set on Media, see ITI TF-2b: 3.32.3.

7.1.3 Dental Document Set Bindings to SEDI

Actors from the ITI XDR and ITI XDM profiles embody the Dental Document Source and Dental Document Recipient sharing function of this Content Specification. The Dental Document Source and Dental Document Recipient shall be grouped with the appropriate actor from the XDR and XDM profiles to exchange the content described here; see DENT TF-1:3.3. The metadata sent in the document sharing or interchange messages has specific relationships or dependencies (which we call bindings) to the content of the clinical document described in the SEDI content profile.

The Dental Technical Framework defines the bindings to use when grouping the Dental

Document Source of this IHE Dental SEDI Content Specification with the Document Source
actor from the IHE ITI XDR Integration Profile.

An SEDI Dental Document Source is grouped with an XDR Document Source for the purpose of sending the Imaging Document Set to an SEDI Dental Document Recipient grouped with an XDR Document Recipient. This binding defines the transformation that generates metadata for the XDSDocumentEntry element of the ITI-41 Provide and Register Document Set-b transaction. The Provide and Register Document Set-b transaction is defined in ITI TF-2b: 3.41.

In addition, an SEDI Dental Document Source may optionally be grouped with an XDM Portable Media Creator for the purpose of sending the Imaging Document Set to a SEDI Dental Document Recipient grouped with an XDM Portable Media Importer. This binding defines the transformation that generates metadata for the XDSDocumentEntry element of the ITI-32 Distribute Document Set on Media transaction using the ZIP over Email option. The Distribute Document Set on Media transaction is defined in ITI TF-2b: 3.32.

The metadata binding is derived from sources including the SEDI Dental Document Set. The content semantics types are specified in the subsections referenced in the following table 7.1.3-1 below:

Table 7.1.3-1: Dental Submission Set Content

| Content | Paragraph |
|-------------------------------|-------------------|
| Sharing of DICOM SOP Instance | DENT TF3: 7.1.5.1 |
| Sharing of PDF Report | DENT TF3: 7.1.5.2 |
| Sharing of text or XML | DENT TF3: 7.1.5.3 |

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| Content | Paragraph |
|----------------|-------------------|
| Sharing of CDA | DENT TF3: 7.1.5.4 |

7.1.4 XDS Metadata

- The Dental Document Source shall support the metadata attribute requirements for the XDS

 Document Repository in an ITI-42 submission as defined in ITI TF-3: 4.3.1 "Requirements on
 Submission Type Transactions" unless otherwise specified below. For a full description of all the
 metadata attributes associated with an XDS document, see ITI TF-3: Table 4.2.3.2-1
 "DocumentEntry Metadata Attribute Definition".
- The Content Modules define the source for all required attributes and optional attributes for dental uses. The Content Modules describe the three main XDS object types: XDSDocumentEntry, XDSSubmissionSet, and XDSFolder. XDSSubmissionSet and XDSDocumentEntry are required. Use of XDSFolder is optional.

7.1.4.1 XDSDocumentEntry Metadata

- Specific SEDI XDSDocumentEntry Metadata Requirements are provided in Table 7.1.4.1-1 and apply to the Dental Document Source. The SEDI constraints include the mapping requirements from the content to the metadata attribute. Note that the Optionality specified in this table supersedes the Optionality specified for other actors in ITI TF-3: Table 4.3.1.1-3 "Metadata Attribute Optionality" where there are differences.
- In order to increase interoperability, the requirements on the Dental Document Recipient remain consistent with an XDR Document Recipient.

Table 7.1.4.1-1: Specific Metadata Requirements for the SEDI Dental Document Source

| Metadata Element | Metadata Attribute | Optionality | SEDI Constraints |
|---------------------|---------------------------|-------------|----------------------|
| DocumentEntry | author: authorPerson | R | |
| DocumentEntry | author: authorInstitution | 0 | |
| DocumentEntry | author: authorRole | 0 | |
| DocumentEntry | author: authorSpecialty | 0 | |
| DocumentEntry | creationTime | R | DENT TF-3: 7.1.4.1.1 |
| DocumentEntry | eventCodeList | R2 | DENT TF-3: 7.1.4.1.1 |
| DocumentEntry | eventCodeListDisplayName | R2 | DENT TF-3: 7.1.4.1.1 |
| DocumentEntry | formatCode | R | DENT TF-3: 7.1.4.1.1 |
| DocumentEntry | mimeType | R | DENT TF-3: 7.1.4.1.1 |
| DocumentEntry | practiceSettingCode | R | DENT TF-3: 7.1.4.1.1 |
| DocumentEntry | serviceStartTime | R2 | DENT TF-3: 7.1.4.1.1 |
| DocumentEntry | sourcePatientInfo | 0 | DENT TF-3: 7.1.4.1.1 |
| DocumentEntry | typeCode | R2 | DENT TF-3: 7.1.4.1.1 |
| DocumentEntry | typeCodeDisplayName | R2 | DENT TF-3: 7.1.4.1.1 |

| Metadata Element | Metadata Attribute | Optionality | SEDI Constraints |
|---------------------|----------------------------------|-------------|----------------------|
| DocumentEntry | uniqueId | R | DENT TF-3: 7.1.4.1.1 |
| DocumentEntry | urn:dent:accessionNumberL ist | О | DENT TF-3: 7.1.4.1.1 |

7.1.4.1.1 XDSDocumentEntry Metadata

- Table 7.1.4.1.1-1 lists XDS document metadata elements that are either further constrained by SEDI, or have SEDI specific instructions for how the Dental Document Source is expected to populate them. Unless otherwise specified, the "optionality" of the attributes listed in the table below is the same as what is required by XDS for the Document Source actor in ITI TF-3: Table 4.3.1.1-3 "Metadata Attribute Optionality".
- For a full description of all the metadata attributes associated with an XDS document, see Table ITI TF-3: 4.3.2.3-1 "DocumentEntry Metadata Attribute Definition".

Table 7.1.4.1.1-1: SEDI-specific Metadata Requirements

| XDSDocumentEntry Attribute | SEDI-specific Requirements | |
|-------------------------------|--|--|
| creationTime | This attribute value shall be populated by the Dental Document Source actor to record the date and time at which the clinical content conveyed in the shared document is created. If the published document is a DICOM object or is transformed from a DICOM information object, this attribute value should be taken from the tags Instance Creation Date (0008,0012) and Instance Creation Time (0008,0013) of the DICOM object. | |
| eventCodeList | This attribute is required to be included in the metadata if known by the Dental Document Source. In other words, it is "promoted" from an optional (O) attribute in XDS to a "required if known" (R2) attribute in SEDI. This attribute shall be populated by the Dental Document Source from code(s) in DCMR Context Group CID 29 for Acquisition Modality and from code(s) in DCMR Context Group CID 4 for Anatomic Region. See DICOM PS 3.16 for DICOM Context Group definitions. This attribute can contain multiple codes and there is not any specific ordering assumed in these codes. | |
| eventCodeDisplayNameList | This attribute is required to be included in the metadata if the eventCodeList attribute is present. This attribute contains the Code Meaning text(s) of the code(s) for Acquisition Modality and for Anatomic Region valued in eventCodeList, from DCMR Context Group CID 29 and from DCMR Context Group CID 4, respectively. See DICOM PS 3.16 for DICOM Context Group definitions. Note that the ordering of the Code Meaning texts populated in this attribute shall be sorted in the same order of the corresponding codes in eventCodeList. | |
| formatCode | This attribute shall be populated by the Dental Document Source from one of the following values: • For a DICOM SOP Instance, this attribute value shall be the DICOM SOP Class UID as the Format Code Value and "1.2.840.10008.2.6.1" (DICOM UID Registry UID) as the Format Coding Scheme OID. | |

| XDSDocumentEntry Attribute | SEDI-specific Requirements | |
|-------------------------------|---|--|
| | "urn:ihe:dent:PDF" for a PDF report document "urn:ihe:dent:XML" for a XML document "urn:ihe:dent:TEXT" for a text document "urn:ihe:dent:CDA" for a CDA document | |
| mimeType | This attribute shall be populated by the Dental Document Source from one of the following values: • "application/dicom" for a DICOM SOP Instance • "application/pdf" for a PDF report • "application/text" for a text document • "application/xml" for a XML document • "application/CDA" for CDA document | |
| practiceSettingCode | This attribute shall be populated by the Dental Document Source by taking a fixed code to designate "Dentistry" | |
| serviceStartTime | This attribute shall be populated by the Dental Document Source for a date and time that indicates the imaging service start time. As an example, the Dental Document Source could take the value of Study Date (0008,0020) and Study Time (0008,0030) from the associated DICOM study | |
| sourcePatientInfo | This attribute shall represent the Patient demographics information used in the Dental Document Source actor system to identify the patient. It is an optional attribute. This attribute allows multiple values for different pieces of patient demographics, see metadata specification in ITI TF-3: Table 4.2.3.2-1.). As an example, this information can be transformed from DICOM Patient's Name (0010,0010), Patient's Birth Date (0010,0030), and Patient's Sex (0010,0040). | |
| typeCode | This attribute shall be populated, if known, by the Dental Document Source actor from a coding system of the Requested Procedure Code of the Requested Procedure, to which the document is associated. | |
| typeCodeDisplayName | This attribute shall be filled by the Dental Document Source actor, if known, using the code meaning text of the corresponding Requested Procedure Code valued in typeCode. | |
| uniqueId | This attribute shall contain the Document unique ID generated by the Dental Document Source actor. It shall be an ISO OID. For a DICOM SOP Instances, this attribute value shall be the same as the SOP Instance UID of the corresponding DICOM SOP Instance. In the future, for a CDA document, this value shall be formulated from the HL7 CDA R2 header as follows: ClinicalDocument/id@root.ClinicalDocument/id@extension | |

495 **7.1.4.1.1.1 XDSDocumentEntry.urn:dent:accessionNumberList**

This attribute may be populated by the Dental Document Source with the Accession Number and assigning authority of the Order Filler for each Order associated with the SEDI Imaging Document Object. SEDI XDSDocumentEntry for a given patientID with a matching 'status' attribute will reference ITI TF-3: Table 4.1-3.

If provided, the urn:dent:accessionNumberList shall include a list of values with the following sub-attributes:

- accessionNumber
- accessionNumberIssuer
- The urn:dent:accessionNumberList identifies the Imaging Service Request of the Originating
 HL7 Imaging Order Message (OMI) Imaging Procedure Control (IPC) Segment, Sequence 1 for
 Accession Identifier. The content may also be found in the DICOM SOP Instance tags,
 (0008,0050) and (0008,0051) when the instances have a single Accession Identifier. The format
 shall conform to the HL7 OMI IPC-1 specification for the Accession Identifier. The
 accessionNumberList may include multiple Accession Identifier values for a single
 XDSDocumentEntry.
 - An example of urn:dent:accessionNumberList containing two values for the Accession Number is as follows:

7.1.4.1.2 Transformation of DICOM VR to XDS Document Metadata Data Types

A number of XDS document metadata attributes use HL7 data types for value representation. Some of the metadata attributes may be transformed from data elements of the corresponding DICOM SOP Instance. SEDI uses RAD TF-3:4.68.4.1.2.3.3 for the transformation of DICOM VR to XDS Document Metadata. Note that term HL7 Data Type in the transformations refers to their specified usage in XDS document metadata as defined in ITI TF-3: Table 4.1-3 "Data Types".

7.1.4.1.3 Submission Set Metadata

The metadata elements in table 7.1.4.1.1-1 shall be used to describe an XDS Submission Set. They shall be provided by the Document Source Actor in the Provide and Register Document Set transaction. They shall be forwarded from a Provide and Register Document Set Transaction. SEDI XDSDocumentEntry submission set metadata will reference ITI TF-3: Table 4.1-3.3-1: SubmissionSet Metadata Attribute Definition. The attribute name is defined with a prefix of the object type of XDSSubmissionSet when referenced by other objects, for example XDSSubmissionSet.sourceId.

7.1.4.1.4 Folder Metadata

The metadata elements in table 7.1.4.1.1-1 shall be used to describe an XDS Folder (if it is implemented as part of exchange). If implemented, they shall be provided by the Document Source Actor in the Provide and Register Document Set transaction. They shall be forwarded from a Provide and Register Document Set Transaction. SEDI XDSDocumentEntry submission set metadata will reference the ITI TF-3: Table 4.1-3.4-1 Folder Metadata Attribute Definition.

7.1.5 Content Specifications

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7.1.5.1 Sharing of DICOM SOP Instance Option

The Dental Document Source shall encode each DICOM SOP Instance in the message as a DICOM Part 10 File.

Dental Document Source and Dental Document Recipient Actors shall support at least one of the DICOM SOP Classes listed in Table 7.1.5.1-1. Other DICOM SOP Classes may also be supported. The Dental Document Recipient must support all SOP classes, and the Dental Document Source is allowed to support a subset. This supports interoperability. Please note there is no DICOM association negotiation.

The complete list of DICOM SOP Classes supported shall be documented in a DICOM Conformance Statement.

Note: This list is provided to highlight the dental related DICOM SOP Classes. It is not intended to be a list that all implementations will support in their products. However, it is required that at least one or more of the relevant SOP Classes listed are implemented.

Note: It is highly recommended that a Dental Document Recipient Actor supports the list of DICOM SOP Classes. This facilitates the ability for the dental practice to be able to view all DICOM SOP instances related to the dental patient.

Note: The MR and US SOP classes are not typically used in dental applications, however future dental use cases based upon imaging of tempormandibular joints (MR), soft tissue salivary glands (US), etc. may be clinically important.

| DICOM SOP Class Name | SOP Class UID |
|--|--------------------------------|
| Digital X-Ray Image Storage - For Presentation | 1.2.840.10008.5.1.4.1.1.1 |
| Digital Intra-oral X-Ray Image Storage - For Presentation | 1.2.840.10008.5.1.4.1.1.1.3 |
| X-Ray 3D Craniofacial Image Storage | 1.2.840.10008.5.1.4.1.1.13.1.2 |
| VL Photographic Image Storage | 1.2.840.10008.5.1.4.1.1.77.1.4 |
| CT Image Storage | 1.2.840.10008.5.1.4.1.1.2 |
| Enhanced CT Image Storage | 1.2.840.10008.5.1.4.1.1.2.1 |
| Computed Radiography Image Storage | 1.2.840.10008.5.1.4.1.1.1 |
| MR Image Storage | 1.2.840.10008.5.1.4.1.1.4 |
| Ultrasound Image Storage | 1.2.840.10008.5.1.4.1.1.7.1 |

Table 7.1.5.1-1: SEDI DICOM SOP Classes

7.1.5.1.1 Compression

Dental Document Source and Dental Document Recipient Actors shall support the ability to Zip and Un-ZIP the set of DICOM Files. However, the DICOM SOP file set is not required to be zipped for the actual transmission.

Note: This allows the dental participants to decide whether this wish to zip the SOP Instances or not.

- The individual SOP Instances within a single DICOM File optionally may be Lossless compressed by the Dental Document Source. Lossy compression is not supported by this profile. The compression choice is conveyed in the DICOM File Meta header Attribute Transfer Syntax UID (0002,0019).
- Not all Actors will support the same types of compression; therefore the Dental Document Source shall be able to transmit the individual SOP Instance uncompressed using the DICOM Transfer Syntax, Explicit VR Little Endian 1.2.840.10008.1.2.1.

Note: For example, a Dental Document Source may send the DICOM SOP Instances compressed (i.e., JPEG 2000, etc.). If the Dental Document Recipient is unable to process the compressed SOP Instance, the Dental Document Source is required to be able to transmit the SOP Instance using Explicit VR Little Endian.

7.1.5.1.1.1 Compression Error Response Message

Dental Document Recipients that support the Dental Exchange of Email option shall send a response message as defined in ITI-TF 2b:3.24.1.2.3 for details on how to manage the response message.

- For instances when the Dental Document Recipient Actor does not support the compression identified in the DICOM File Header, it shall return the following [MDN] error response:
 - Error: the MDN "disposition-type" field is set to "deleted" and the MDN "disposition-modifier" is set to "Error: proposed transfer syntax not supported"

7.1.5.2 Sharing of PDF Report Option

There are no requirements for a specific version of PDF. However, it is recommended to use the PDF/A (ISO 19005-1).

7.1.5.3 Sharing of text or XML Option

No formatting requirements are placed on XML and text.

Appendices

590 None

Volume 3 Namespace Additions

None

Volume 4 – National Extensions

Add appropriate Country section

4 National Extensions

None

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