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SERIES H: AUDIOVISUAL AND MULTIMEDIA SYSTEMS

E-health multimedia services and applications – Personal health systems

Interoperability design guidelines for personal connected health systems: Healthcare Information System interface

Recommendation ITU-T H.813

International Telecommunication Union

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Recommendation ITU-T H.813

Interoperability design guidelines for personal connected health systems: Healthcare Information System interface

Summary

The Continua Design Guidelines (CDG) defines a framework of underlying standards and criteria that ensure the interoperability of devices and data used for personal connected health services. The Continua Design Guidelines also contains design guidelines (DGs) that further clarify underlying standards or specifications by reducing options or by adding missing features to improve interoperability.

ITU-T H.813 focuses on the following interface:

– HIS-IF – Interface between Health & Fitness services (HFS) and the Healthcare Information System (HIS)

ITU-T H.813 is part of the "ITU-T H.810 interoperability design guidelines for personal connected health systems" subseries that covers the following areas:

– ITU-T H.810 – Interoperability design guidelines for personal connected health systems: Introduction

– ITU-T H.811 – Interoperability design guidelines for personal connected health systems: Personal Health Devices interface

– ITU-T H.812 – Interoperability design guidelines for personal connected health systems: Services interface

– ITU-T H.812.1 – Interoperability design guidelines for personal connected health systems: Services interface: Observation upload capability

– ITU-T H.812.2 – Interoperability design guidelines for personal connected health systems: Services interface: Questionnaire capability

– ITU-T H.812.3 – Interoperability design guidelines for personal connected health systems: Services interface: Capability exchange capability

– ITU-T H.812.4 – Interoperability design guidelines for personal connected health systems: Services interface: Authenticated persistent session capability

– ITU-T H.813 – Interoperability design guidelines for personal connected health systems: Healthcare Information System interface design guidelines (this design guidelines document)

History

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Keywords

CDG, continua design guidelines, healthcare information systems, personal connected health systems, personal health devices, services.

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FOREWORD

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The World Telecommunication Standardization Assembly (WTSA), which meets every four years, establishes the topics for study by the ITU-T study groups which, in turn, produce Recommendations on these topics.

The approval of ITU-T Recommendations is covered by the procedure laid down in WTSA Resolution 1.

In some areas of information technology which fall within ITU-T's purview, the necessary standards are prepared on a collaborative basis with ISO and IEC.

NOTE

In this Recommendation, the expression "Administration" is used for conciseness to indicate both a telecommunication administration and a recognized operating agency.

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As of the date of approval of this Recommendation, ITU had not received notice of intellectual property, protected by patents, which may be required to implement this Recommendation. However, implementers are cautioned that this may not represent the latest information and are therefore strongly urged to consult the TSB patent database at http://www.itu.int/ITU-T/ipr/.

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0 Introduction

The Continua Design Guidelines (CDG) defines a framework of underlying standards and criteria that ensure the interoperability of devices and data used for personal connected health services. The CDG also contains design guidelines (DGs) that further clarify the underlying standards or specifications by reducing options or by adding missing features to improve interoperability.

This design guidelines focuses on the following interface:

– HIS-IF – Interface between Health & Fitness services (HFS) and the Healthcare Information System (HIS).

This design guidelines is part of the "ITU-T H.810 interoperability design guidelines for personal health systems" subseries. See [ITU-T H.810] for more details.

0.1 Organization

This design guidelines document is organized in the following manner.

Clauses 0 to **5: Introduction and terminology** – These clauses provide useful background information to help understand the structure of the design specifications.

Clause 6: HIS interface design guidelines – This clause is an overview of the HIS-IF architecture and design guidelines for the Health & Fitness services (HFS) and the Healthcare Information System (HIS) implementing the Healthcare Information System interface (HIS-IF).

0.2 Guideline releases and versioning

See clause 0.2 of [ITU-T H.810] for release and versioning information.

0.3 What's new

To see what is new in this release of the design guidelines refer to clause 0.3 of [ITU-T H.810].

1 Scope

This design guidelines document focuses on the following interface:

– **HIS-IF** – Interface between Health and Fitness Services (HFS) and the Healthcare Information System (HIS).

This interface is defined in the Continua architecture as described in clause 6 of [ITU-TH.810] and is illustrated in Figure 6-1.

2 References

The following ITU-T Recommendations and other references contain provisions which, through reference in this text, constitute provisions of this Recommendation. At the time of publication, the editions indicated were valid. All Recommendations and other references are subject to revision; users of this Recommendation are therefore encouraged to investigate the possibility of applying the most recent edition of the Recommendations and other references listed below. A list of the currently valid ITU-T Recommendations is regularly published. The reference to a document within this Recommendation does not give it, as a stand-alone document, the status of a Recommendation.

[ITU-T H.810] Recommendation ITU-T H.810 (2017), *Interoperability design guidelines for personal connected health systems: Introduction*.

All other referenced documents can be found in clause 2 of [ITU-T H.810].

3 Definitions

This design guidelines document uses terms defined in [ITU-T H.810].

4 Abbreviations and acronyms

This design guidelines document uses abbreviations and acronyms defined in [ITU-T H.810].

5 Conventions

This design guidelines document follows the conventions defined in [ITU-T H.810].

6 HIS interface design guidelines

6.1 Architecture

6.1.1 Overview of the HIS-IF

The purpose of the HIS interface is to transfer patient information from a Continua health and fitness service (containing the HIS Sender) to either another health and fitness service or another health information service (containing the HIS Receiver). The health and fitness service can be the remote patient monitoring (RPM) server of a disease management service provider or the application server of an ageing independently or health and fitness service provider. The patient information for transfer may include a report summarizing the patient's current status, a detailed listing of specific patient results, readings from one or more personal health devices (PHD), or a combination of these. The health information service may contain a hospital's enterprise health record (EHR), a physician's electronic medical record (EMR) or a personal health record (PHR) service used by the patient.

Figure 6-1 represents the HIS interface relative to the Continua end-to-end (E2E) architecture.

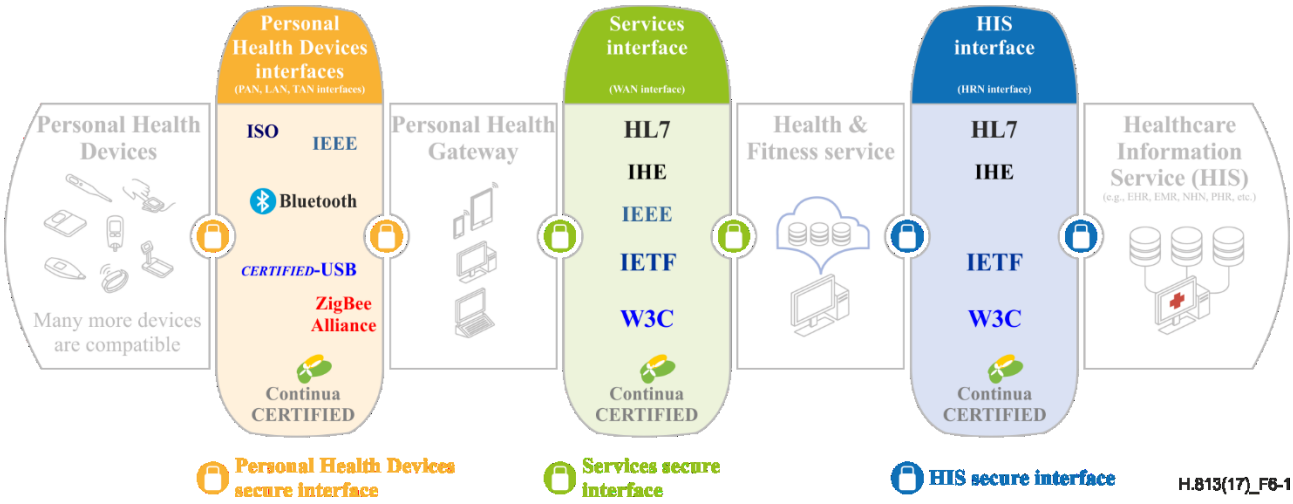

Figure 6-1 – HIS interface in the Continua E2E architecture

At a higher level, there are different functional blocks that make up the HIS interface. Figure 6-2 illustrates this view of the architecture.

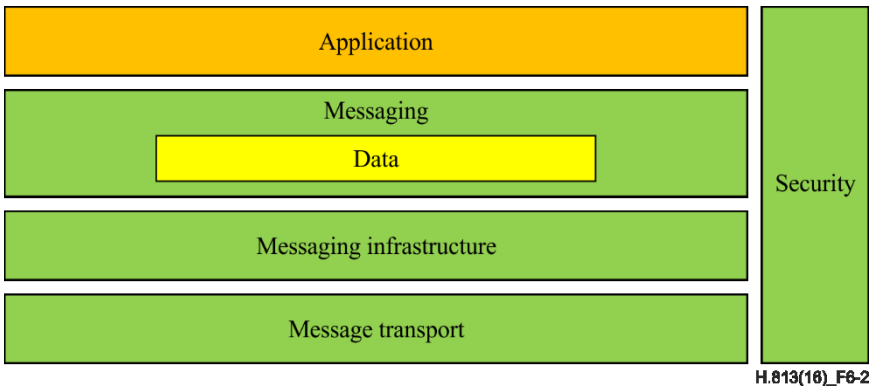

Figure 6-2 – HIS functional blocks

The applications block contains enterprise healthcare applications such as a remote patient monitoring (RPM) system hosted by a disease management service provider or an EMR system at a physician's office. The data block contends with the format of the actual data transmitted between the applications. It may be in coded format, free-text, or a combination of both.

The messaging block handles how data is packaged to ensure consistency and readability across multiple transport methods. The messaging infrastructure deals with the infrastructure needed to transport this information model, such as MLLP, FTP, web services and others. The message transport layer forms all the layers below the transport layer of the OSI stack. The security block ensures that the messages exchanged between applications are secure.

6.1.1.1 Purpose of HIS interface guidelines

The HIS interface guidelines describe how Continua-certified health information services can exchange patient information with other Continua-certified health information services or with non-Continua electronic health record (EHR) systems. Figure 6-3 is a high level view of the scope of these guidelines.

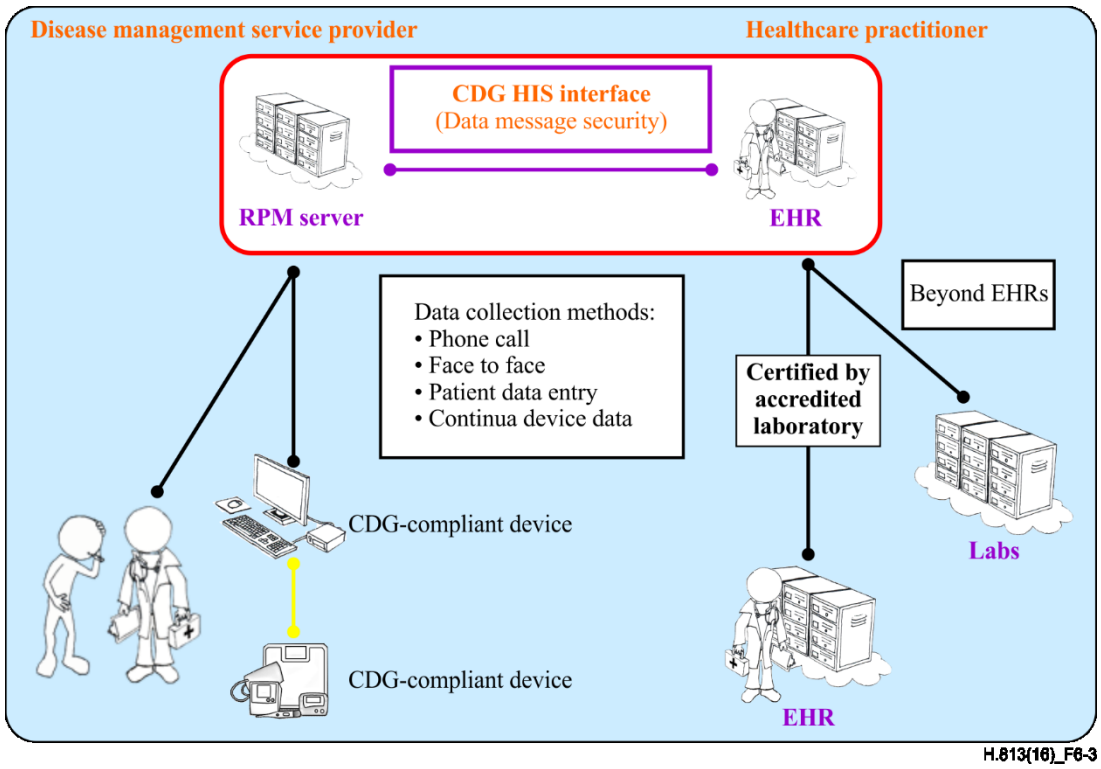

Figure 6-3 – User scenario for the HIS interface

The purpose of these guidelines is to establish the basic standards, rules and restrictions in the data, message and transport protocols necessary to enable the transfer of pertinent information from a Health & Fitness service with a HIS-IF (HIS sender) to another Health & Fitness service with a HIS-IF (HIS receiver) or to a healthcare practitioner, system or setting (HIS receiver). This pertinent information is obtained from the following sources:

Personal Health Devices (PHDs): This includes relevant vital measurements that the sending and receiving entities agree are relevant to the patient's condition.

Remote patient monitoring (RPM) service provider: This includes updates/notes/summary information that is sent by a remote monitoring service provider. The notes include information and progress updates relevant to the particular condition for which the patient is being monitored.

Patient data entry: This includes patient notes or notes interpreted by a nurse after talking to the patient.

Identification/Demographics: This may include patient identification information, device identification and other registration information.

6.1.1.2 Chosen standards and profiles

Data: To facilitate the accurate transfer of both coded patient results from Personal Health Devices and textual summary results from patient care-givers, the HL7 Personal Healthcare Monitoring Report document format standard was chosen.

NOTE – The data guidelines are based on the HL7 CDA R2 standard [HL7 CDA-PHMR], profiled by the *HL7 Personal Healthcare Monitoring Report (PHMR) Implementation Guide*.

Patient identity: To ensure that HIS senders and receivers can correctly associate personal health data with the right patient, the IHE patient identifier cross-reference (PIX) profile was selected. This profile provides a standards-based interface for managing identifiers across organizational and political domains.

HIS senders must implement the IHE patient identity feed transaction in order to provide the necessary information for cross-referencing. This cross-referencing must then be performed from a patient identifier cross-reference manager either within the destination's domain of control, or shared between the sending and receiving entities, such as in the case of an XDS-based healthcare information exchange (HIE).

Using an IHE PIX query of the cross-reference manager, senders and receivers are able to map between their local identifiers and those identifiers used for sharing/transfer.

The PIX profile is widely used in conjunction with the XDS family of specifications to implement integration scenarios within and between hospital enterprises, such as in the case of a disease management organization sending patient monitoring information to a healthcare information exchange. However, the profile is also applicable in the ageing independently and health and fitness domains, when a particular organization's local identifiers must be mapped to a receiving system's identifiers, such as in the case of a physical therapy organization sharing fitness data with a member's primary care physician.

It is important to note, however, that in certain circumstances, the use of a patient identity cross-reference manager may not be required or appropriate. For instance, in cases where there is no party suited to perform the management of patient cross-references (as in certain personal health record integration scenarios), the HIS sender and receiver must agree on a patient identification scheme that is suitable for their particular use case.

In general, PIX queries are most appropriately used for direct machine-to-machine interaction where a system needs to locate a patient's global enterprise ID for reference against other clinical information stored against that ID. Here, the patient's ID assignment and device allocation is clearly known.

PDQ queries are likely to be most appropriate for user-driven interactions such as a physician searching for a patient's history alongside recent monitoring data, who may execute a search by name where a potential list of matches may be returned and then the physician drills further into each patient identity record to locate the exact match of information.

Messaging: A future is envisioned where patient information is sent between providers by various methods. These methods include: secure direct connection over the Internet, secure e-mail, delivery on portable media (data stick, etc.), through a messaging hub and through a data repository or RHIO/NHIN.

To facilitate this, a messaging standard capable of supporting all five transport methods with a minimal amount of rework was chosen. That is, once the first transport method is accomplished, incorporating additional transport methods requires less work.

In addition, because this interface is used to communicate with non-Continua certified electronic health records, a messaging standard supported by others that certify electronic health record systems was chosen.

For these reasons, the "Integrating the Healthcare Enterprise's (IHE) Cross-Enterprise Document Sharing (XDS)" profile was chosen.

Transport protocol: To accomplish secure direct communication of pertinent patient information between care-givers, the IHE cross-enterprise document reliable interchange (XDR) profile utilizes current standards such as SOAP 1.2 and MTOM.

To accomplish secure indirect communication of pertinent patient information between care-givers, the IHE cross-enterprise document media interchange (XDM) profile utilizes current standards such as Zip and S-MIME.

NOTE – Because the HIS sender and HIS receiver are likely to be on separate local networks, the HIS sender may send the patient information to the HIS receiver across the public Internet. Therefore, both the HIS sender and the HIS receiver may require Internet access and the equipment (hardware and software) necessary to securely send the patient's information across the Internet using the transport method detailed in these guidelines. If the HIS sender and HIS receiver are on the same secure network, or if a secure network connection exists between their networks (i.e., a VPN connection), then Internet connectivity is not required.

6.1.1.3 HIS topology

The HIS interface defines a means of communication between a HIS Sender (client component) and a HIS Receiver (service component). The communication is initiated by the sender and the receiver acknowledges the receipt of the data (if the communication protocol allows, as XDR does).

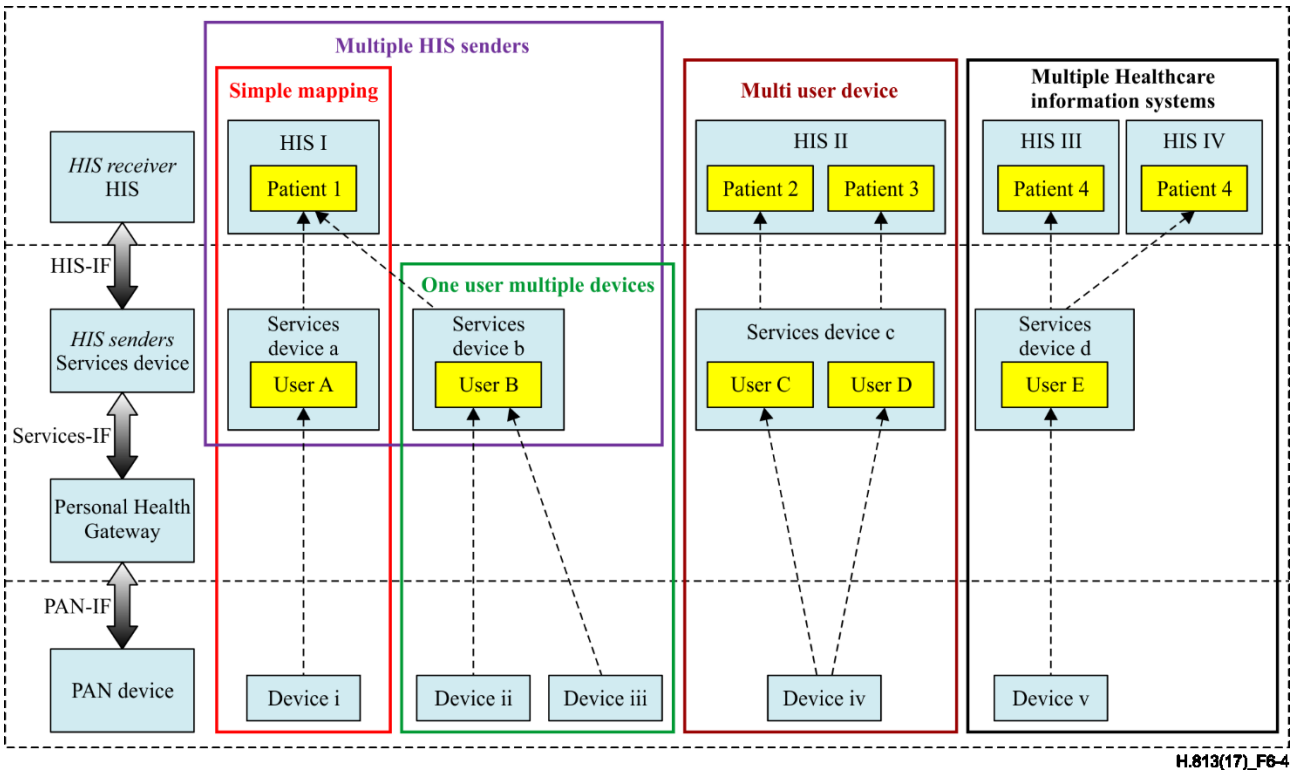

Figure 6-4 – HIS topology

Figure 6-4 displays the topology for the HIS interface communication. The context of communication is always related to a patient. The patient identification method is negotiated between the HIS Sender and the HIS Receiver through registration within a patient identity cross reference manager utilizing the IHE patient identity feed. It is important to note that the patient identification is not necessarily globally unique, but rather it is specific to the particular instance of HIS communication. For example, the same person can be identified differently in distinct HIS Receiver systems and therefore, the appropriate patient identification should be used for each respective HIS interface communication. To this end, HIS Senders are required to implement the IHE patient identity source actor, defined by transaction ITI-44: Patient Identity Feed HL7 V3 of the IHE IT Infrastructure (ITI) Technical Framework supplement, in order to provide HIS Receivers with the patient information needed to create and maintain accurate cross-referencing. As illustrated in the HIS topology diagram (Figure 6-4), the HIS Sender and HIS Receiver must take into consideration various case scenarios when considering and communicating patient identification. These case scenarios include but are not limited to:

– **Simple mapping** – where one PHMR containing data from a single PHD is sent to a single HIS receiver. The patient identifier to be used is obtained via a PIX query, an out-of-band agreement and/or provided previously to the HIS receiver via a patient identity feed HL7 V3 message.

– **One user multiple PHDs** – similar to the simple mapping case, data from multiple PHDs for a single patient is transferred over the HIS protocol within a single PHMR.

– **Multiple HIS senders** – this case describes the situation where the HIS receiver accepts PHMRs from multiple HIS senders for the same patient. Each sender delivers independent messages with the patient properly identified and with data from PHDs specific to that HIS sender.

– **Multi user PHD** – the HIS sender is delivering data for multiple patients in separate PHMRs for each patient, even though the data originated from a single PHD.

– **Multiple health providers** – in this case, the HIS sender delivers data for one patient from one (or more) PHD(s) to multiple HIS receivers. Each HIS receiver receives its own PHMR for that patient. The pertinent information in these reports may be identical, however, each contains the patient identification agreed to and appropriate for the agreement between that HIS sender and that HIS receiver.

The above list describes some of the basic cases. The real world situation can be a combination of these described cases. For example, one patient's data can be present in reports from multiple HIS senders and submitted to several HIS receivers.

6.1.2 Messaging infrastructure and transport standards

The messaging infrastructure guidelines describe how the messages will be transported between the HIS Sender and the HIS Receiver. They also describe the infrastructure that will be necessary to accomplish the selected transport method (see Figure 6-5).

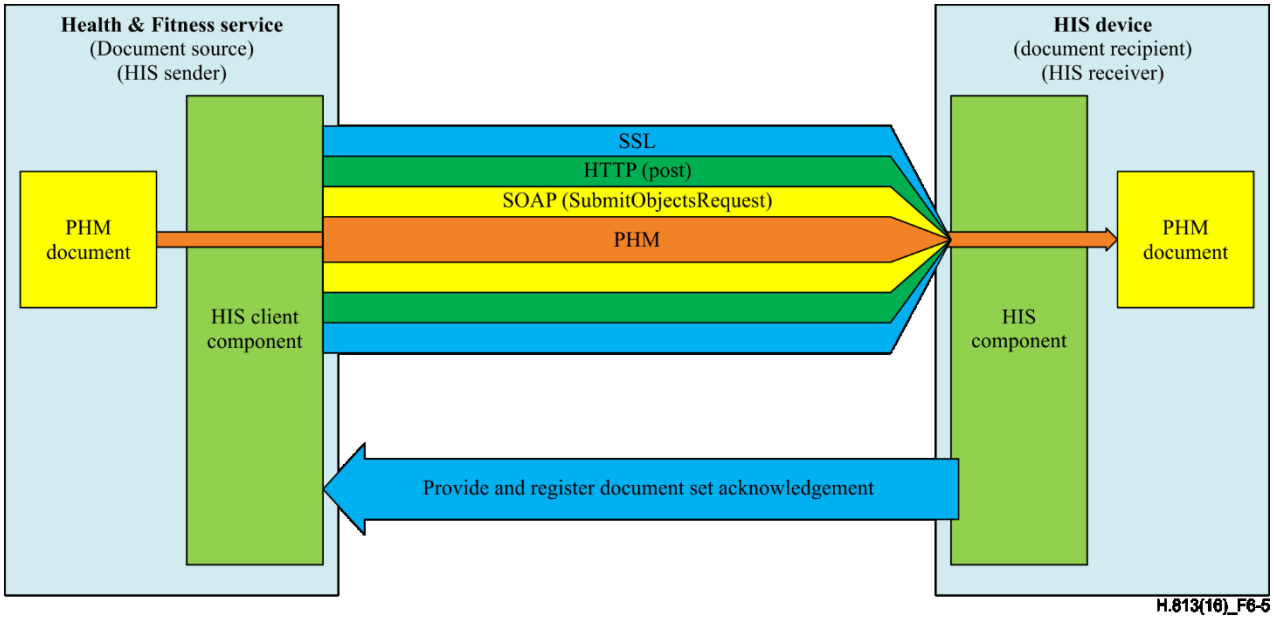

Figure 6-5 – Direct HIS messaging via XDR

For v1, the IHE's cross-enterprise document reliable interchange (XDR) [IHE ITI TFS XDR] profile was selected as the transport method for direct communications across the HIS interface. This profile is a member of IHE's XDS family of profiles. As such, it uses the same HTTP, SOAP 1.2, ebXML and MTOM standards set forth in IHE's XDS.b guidelines, for more information, see [IHE ITI TFS XDR].

As noted in the overview above, special attention must be given to the infrastructure required to accomplish this transport method. The XDR profile contains no intermediate data repository or messaging hub. If the communication between the HIS Sender and the HIS Receiver will occur over the Internet, then the HIS Receiver will need to be Internet-facing. In other words, the system receiving the messages on the HIS interface will need to be reachable from the HIS Sender. If the HIS Sender is not on the same secure network as the HIS Receiver and a secure connection does not exist between their networks, then the HIS Receiver will need to be reachable from anywhere on the Internet and its IP address accessible to everyone on the Internet.

From an implementation standpoint, the HIS Receiver may be the provider's electronic health record system itself, or it may be a web-front-end system whose purpose is to securely carry the messages across the providers firewall boundary without exposing the electronic health record to

the perils of the Internet. This second method provides additional security for the provider and patient data and therefore it should be duly considered by system integrators.

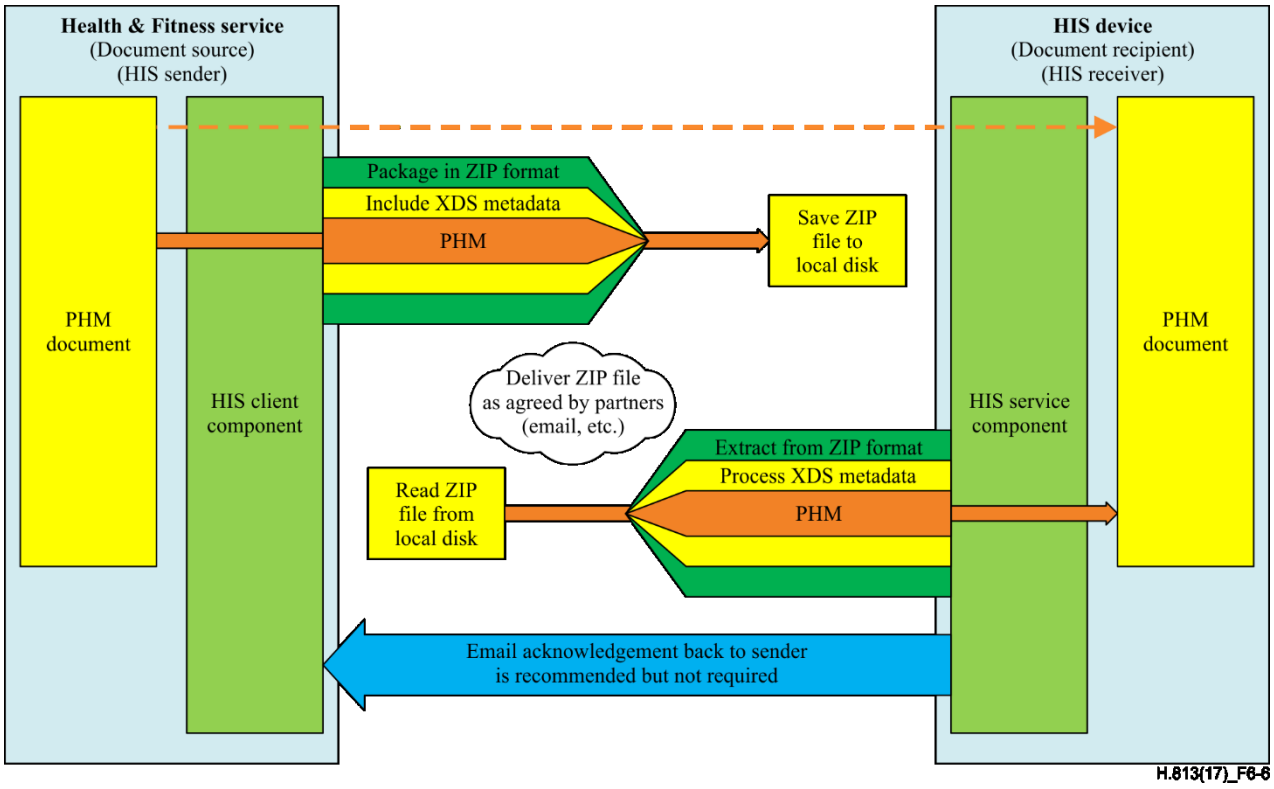

Figure 6-6 – Indirect HIS messaging via XDM

IHE's cross-enterprise document media interchange (XDM) profile [IHE ITI TFS XDM] was added in the CDG as the transport method for indirect communications (via e-mail or physical media) across the HIS interface. This profile is a member of IHE's XDS family of profiles. For more details, see [IHE ITI TFS XDM].

The infrastructure required to accomplish XDM is different and likely to be less complicated than for XDR.

Selecting which transport method (XDR or XDM) to use is left up to the system integrator. While XDR is clearly the more optimal choice because it provides faster communications, XDM can be much easier to implement, allowing the delivery of PHMRs to occur over an existing e-mail infrastructure with little, if any, new equipment or software.

6.1.3 Messaging and selected standards

For messaging and transport, the HIS-IF utilizes as its base the integrating the healthcare enterprise [IHE] cross-enterprise document sharing (XDS) family of profiles. This family of profiles thoroughly covers the spectrum of communication requirements for a large health information network such as a regional health information organization (RHIO). In particular, the XDR and XDM profiles from this family are used because they explicitly target a simple point-to-point exchange of documents. When combined with the IHE patient identifier cross-reference (PIX) profile, these profiles enable the safe transfer of a single document set against the correct patient identity.

An important aspect of the chosen standards is for a common set of meta-data that is specified and describes the PHMR being transmitted. This metadata is utilized by holders of the document to help determine how to handle the document without the need to open, resolve all referenced attached

documents, parse and examine the contents. Thus, the meta-data allows the holders to rapidly determine the best way to handle a document quickly and easily.

This metadata takes the form of a concretely defined list of required information. The metadata contains pertinent data such as authorship description (e.g., person, role, institution), document description (e.g., date, time, language) and patient identification and demographics (PID, name, address).

This information is then mapped to the appropriate form of the specific transport. In v1, this information takes the form of XML that will map to the ebXML that overlays the simple object access protocol (SOAP) envelope. Thus, it is present in the SOAP header and body clauses where it is easily accessible on reception (see Figure 6-5). With the addition of XDM (sending data via e-mail attachment or removable media) in this version of the guidelines, the meta-data is stored in the top-level directory of the exported file package that is created when the PHMR is exported for delivery via the XDM method. Because of this, the exported file package must first be opened or extracted before the meta-data can be accessed (see Figure 6-6). The particular file packaging format called out by XDM is the ZIP format. Applications and programming libraries to create and read ZIP files are widely available and on many operating systems. Licensing costs will need to be confirmed; but may be covered by the purchasing of the application or library used to create or read the ZIP file.

6.1.4 Data and selected standards

The data transmitted from the HIS sender can be either summary, raw data or both. The summarization may be a result of analysis by an authentic disease management service provider. The data has multiple characteristics that include:

1. Representation of measurements captured by PHDs.
2. Representation of notes, summary and other kinds of narrative information that are added by care givers or by the user themselves.
3. Representation of graphs that are added by intermediary services that represent the trends of a user's health.
4. Patient information that allows endpoints to catalogue the aforementioned data against existing patient records.

To accommodate the wide variety of data characteristics, the HL7 clinical document architecture (CDA) [HL7 CDA-PHMR] based format is chosen. The CDG specifies constraints on the CDA in accordance with requirements set forward by the HIS interface. These constraints are henceforth called the personal healthcare monitoring report (PHMR).

Wherever possible, the PHMR reuses the templates already set forth by a HL7 specification called continuity of care document (CCD) [HL7 CDA-CCD]. The reasons for reusing the CCD templates are:

1. The CCD templates already contain a number of constraints that are needed by the HIS interface.
2. The CCD is a harmonized specification of CDA (based on HL7 V3 RIM) and the ASTM E2369-05 standard specification for continuity of care record (CCR), see [HL7 CDA-CCD].
3. Since the CCD has gained relevance in the marketplace, it is best if the PHMR is derived from the CCD so that it is a lesser burden to the EHR implementations that are designed to work with the CCD.

The *HL7 Personal Health Monitoring Report Implementation Guide* [HL7 CDA-PHMR] has an independent lifecycle under a project called the "Personal Health Monitoring Report" under the HL7 Structured Documents Workgroup (SDWG).

6.1.5 Security

The five archetypal high-level areas of security requirements are a subset of 11.2.3 of [b-ISO 27000] and are as follows:

– **Authorization** – Only fully identified and authenticated entities, equipped with access control credentials, should be able to avail themselves of services provided by systems.

– **Accountability** – Users should be fully accountable for (and unable to repudiate) their actions. It should be possible to determine, through a system's accountability features, who performed any given action and which actions have taken place in a specified interval.

– **Availability** – A system should be available for use when required for critical operations. Critical data should be available when required. The data and keys associated with encryption for the purposes of confidentiality should be recoverable.

– **Administration** – Responsible security policy authorities should have secure, usable interfaces for defining, maintaining, monitoring and modifying security policy information.

– **Assurance** – It should be possible to demonstrate to a sceptical observer that a system actually provides the claimed level of protection with periodic validation and that the protection is still effective.

6.1.6 Transport security

The HL7 clinical document architecture (CDA) [HL7 CDA-PHMR], which is the basis for PHMR implementation, relies on the transport mechanism to implement security and authentication. The CDA does provide confidentiality status information to aid the application systems in managing access to sensitive data.

The IHE XDS profile family assumes that a suitable security and privacy environment was established and that the relevant threats are managed by agreements and implemented by generic security mechanisms not unique to XDS.

For direct communications, the transport security of the HIS interface is accomplished by the adoption of the security solution from the IHE XDR profile and its prerequisite industry standards. For indirect communications via the IHE XDM profile, the transport security depends on the final delivery method employed. If the exported file is delivered to the HIS receiver via e-mail (the recommended method), then S-MIME is used to ensure security. However, the cases in which the ZIP-packaged PHMR is further stored on removable media (i.e., USB, drive, CD-ROM, etc.) or transferred via FTP are not covered in this guideline and require their own security considerations.

In addition, the XDS profiles assume that implementers of the document source and document recipient have in place an agreement that defines when they interchange the PHMR data and how to manage the inconsistencies between security policies in both organizations. The XDS profiles further require the reconciliation of patient identification upon import of the document.

The CDG specifications for the HIS sender further narrow these framework provisions to allow reasonable design guidelines. However, it should be noted that the final security implementation must be designed by the communicating parties.

6.1.7 Document-level integrity, data origin authentication and non-repudiation

Integrity, data origin authentication and non-repudiation are important security properties for personal healthcare monitoring report (PHMR) documents exchanged over the HIS-IF. Through the

use of transport security (TLS, IHE ATNA) basic integrity and node authentication is realized. However, non-repudiation requires additional measures such as a signature over the documents. This also strengthens the integrity property as a signature can protect the integrity of the document independent of how it is exchanged and thereby provides end-to-end integrity if it is exchanged multiple times.

For the HIS-IF integrity, data origin authentication and non-repudiation are realized through the use of IHE document digital signature content profile. IHE DSG allows signing of documents in a submission set exchanged using the protocols in [IHE ITI TF-1 XDM] and [IHE ITI TFS XDR].

Non-repudiation enabled HIS sender is a HIS sender that deploys security operations to assure that data integrity, data origin authentication and data origin non-repudiation properties are preserved when transmitting an observation document. **Non-repudiation enabled HIS receiver** is a HIS receiver that deploys security operations to assure that data integrity, data origin authentication and data origin non-repudiation properties are preserved when receiving an observation document. In other words, these security operations are mandatory only for non-repudiation enabled HIS senders and receivers. This makes the decision to apply such measures a business decision based on risk assessments. It is a choice of a HIS receiver to deploy these security constructs should the need arise to enable interoperability with non-repudiation enabled HIS senders.

6.1.8 Consent management

Consent in healthcare includes concepts like opt-in, opt-out and secondary use and enables patients to regulate which care providers have access to which health information. Capturing consent in digital form increases consistency, compliance and efficiency for both patients and care providers.

Consent management at the HIS-IF supports scenarios where a patient holds a consent policy at a Health & Fitness service which should also be applied at a HIS service. An example is a scenario where a patient defines his consent at a disease management organization and a condition occurs that requires involvement of another doctor. In such a case a nurse may, if permitted by the consent policy, forward his record together with the consent document allowing the receiver to use the information in accordance with the patient's consent policy. In a variant, a HIS service may seek additional consent from the patient. Instead of Health & Fitness service to HIS exchanges, consent documents may also be exchanged from HIS to HIS services.

For the HIS-IF the scope is limited to the exchange of the consent documents between the HIS sender and HIS receiver. The creation and management of the consent documents is out of the scope of this design guideline. It is the assumption that patients have already given their consent, e.g., to a disease management organization.

The consent enabled HIS sender is a HIS sender that is capable of transmitting a patient consent document. The consent enabled HIS receiver is a HIS receiver that is capable of receiving a patient consent document. Support for consent management is mandatory for consent enabled HIS senders and receivers.

Consent management at the HIS-IF is based on the HL7 CDA R2 consent directive [HL7 CDA IG] to capture patient consent in a CDA consent document. Two types of interaction are provided to exchange consent documents. The first extends the existing IHE XDR transaction to exchange the PHMR document by including the consent document in the submission set. Figure 6-7 provides an overview of this interaction. The IHE XDR profile is based on the ITI-41 Provider and Register document Set-b transaction. An exchange transaction here may concern a new consent document or update.

The second interaction follows a request/response structure to obtain the consent document separate from the PHMR document. This interaction may be used e.g., in cases where a reference to already shared consent documents suffices or situations where a consent document should be obtained because it is not available (anymore) for a particular patient or record. The HIS receiver uses IHE

XDS to send a request for a given consent document to the HIS sender which then responds with the referenced consent document. Figure 6-8 provides an overview of this request-response interaction. The IHE XDS profile employs the ITI-43 Retrieve Document Set.b transaction and the ITI-18 Registry Stored Query transaction to facilitate lookup document identifiers and location URLs.

A HIS sender has knowledge of the applicable patient consent for a PHMR document and signals this to a HIS receiver using the ConfidentialityCode field in the PHRM document, which identifies the applicable consent document, thereby associating the consent document to the health data.

To properly authenticate the requester and personalize the PHMR and patient consent document, the actual user (care provider) is authenticated rather than a HIS receiver node. This allows for the selection and issuing of the appropriate consent, e.g., the consent based on or belonging to the functional role of a nurse or doctor. Such consent modified to the situation also allows for exceptions for particular users and records thereby tailoring the access to the record. The authentication uses IHE XUA to include a SAML token in the ITI-43 Retrieve Document Set.b request message (see Figure 6-9), which is used to request a consent document.

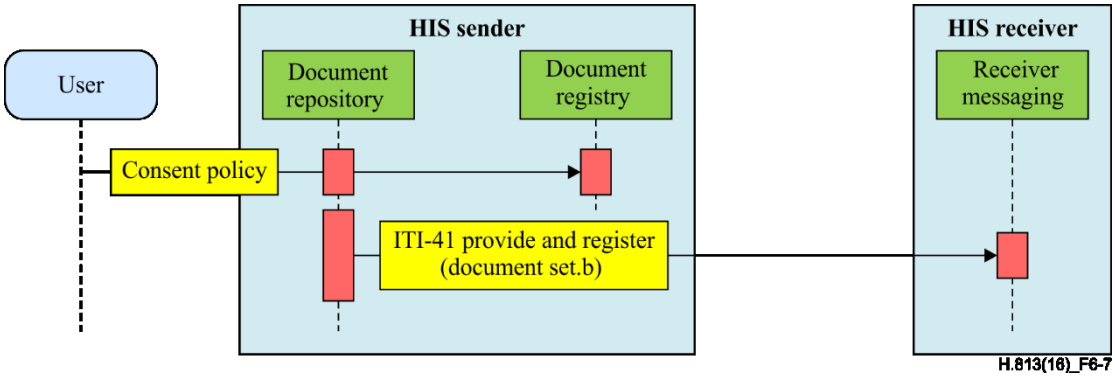

Figure 6-7 – Point-to-point interaction to exchange consent using IHE XDR at HIS-IF

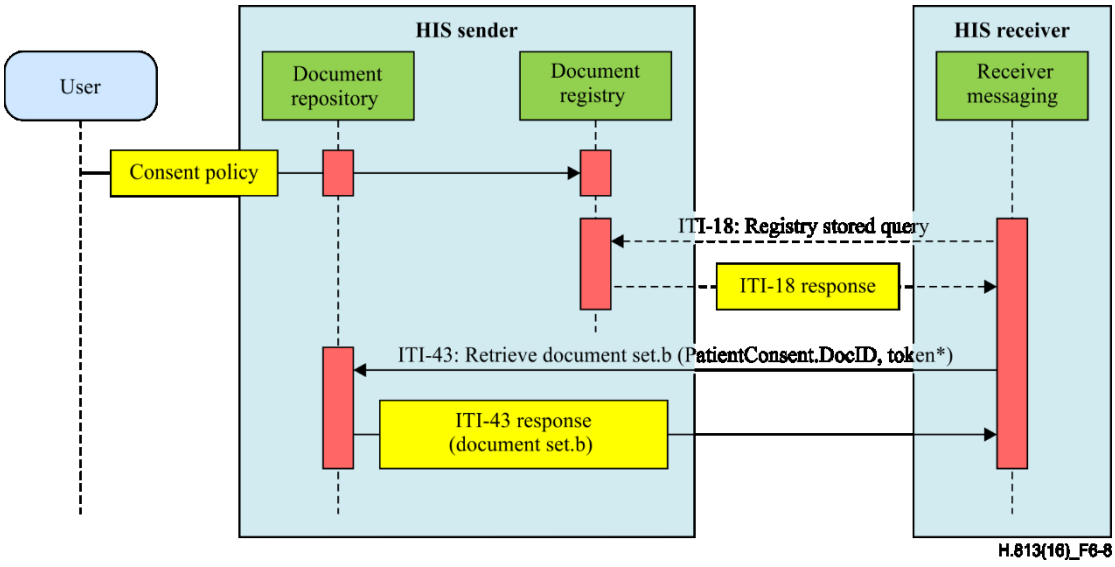

Figure 6-8 – Request-response interaction to obtain consent using IHE XDS at HIS-IF

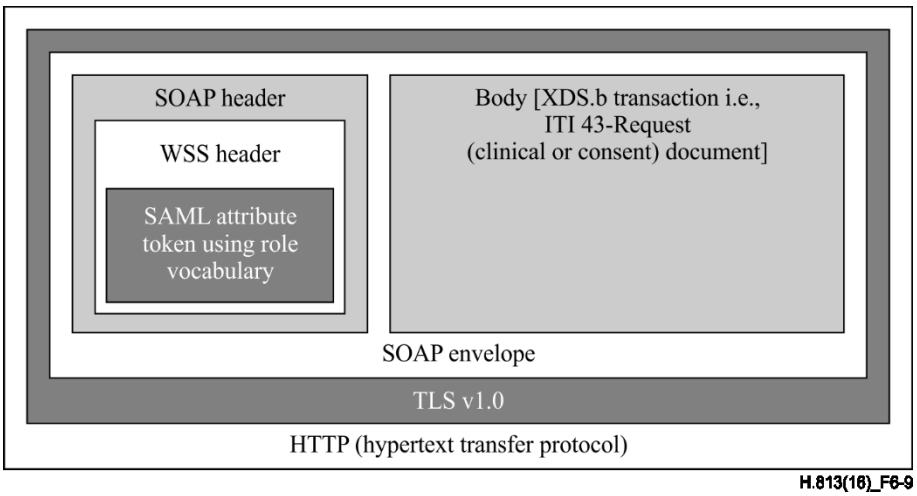

Figure 6-9 – SAML encapsulation and the overall protocol stack

6.1.9 Consent enforcement

The CDG enables the enforcement of patient consent through encryption on a consent enabled HIS. The consent enabled HIS sender is a HIS sender that is capable of specifying patient consent according to HL7 CDA R2 consent directive [HL7 CDA IG], encrypting the PHMR document for a recipient(s) and transmitting them on the HIS-IF. The consent enabled HIS receiver is a HIS receiver that is capable of receiving patient consent documents and encrypted PHMR documents.

The IHE document encryption (DEN) profile is used to enable consent enforcement through encryption. IHE DEN enables encryption of a PHMR document for a specific recipient (e.g., doctor or nurse) at the consent enabled HIS receiver. This protects the privacy of the patient in an efficient manner and makes sure that the PHMR document is viewed only by the intended recipient. This prevents the viewing of the PHMR document by other individuals who may be working in the same organization e.g., administrative staff.

Figure 6-10 provides an overview of different steps employed in order to exchange encrypted PHMR document(s) on the HIS-IF using the IHE XDR profile. The only new feature that is added compared to Figure 6-7 (i.e., consent management guidelines) is the encryption of the PHMR document(s). The consent enabled HIS sender has to at least support the PKI based key management method from the IHE DEN profile. This means that the content encryption key is encrypted with the public key of the recipient. The consent enabled HIS sender may also support other key management methods such as password based key management methods. However, the consent enabled HIS receiver is required to support all key management methods specified in the IHE DEN profile. Before encrypting a PHMR document, the consent enabled HIS sender has to construct the XDS metadata for the PHMR document. A submission set is created which consists of an encrypted PHMR document and a patient consent document. The submission set is then transported using the IHE XDR profile (i.e., ITI-41 Provider and Register Document Set.b). Figure 6-11 shows the application of the IHE DEN profile during the request/response interaction in order to enable patient consent enforcement. The requester is being authenticated and the patient consent is being evaluated. If the result of the authentication and the evaluation of patient consent are positive, then a personalized consent document is created based on the functional role of the requester. The PHMR document is then encrypted for the requester and a submission set is created which consists of a personalized consent document and an encrypted PHMR document. The submission set is then transported through an ITI-43 Response transaction.

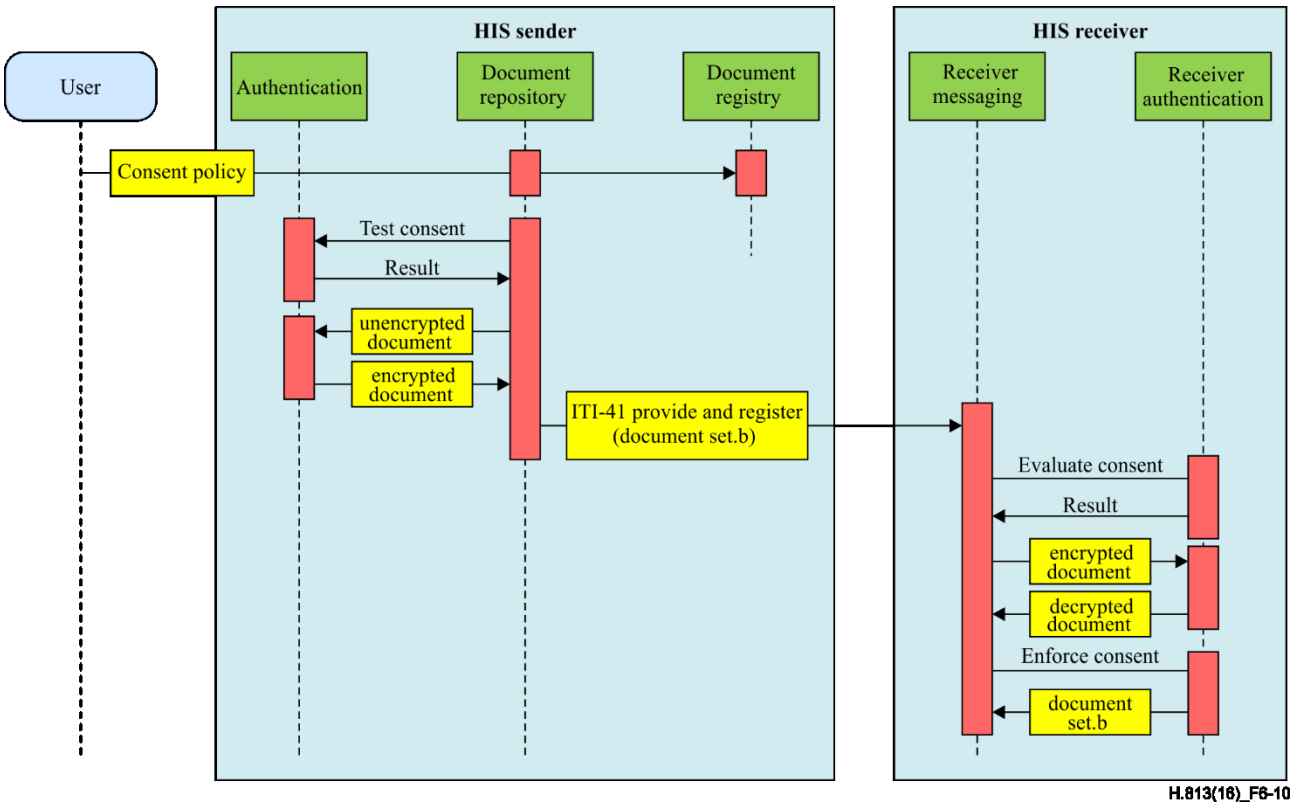

Figure 6-10 – Point-to-point interaction to exchange encrypted PHMR documents along with consent using IHE XDR at HIS-IF

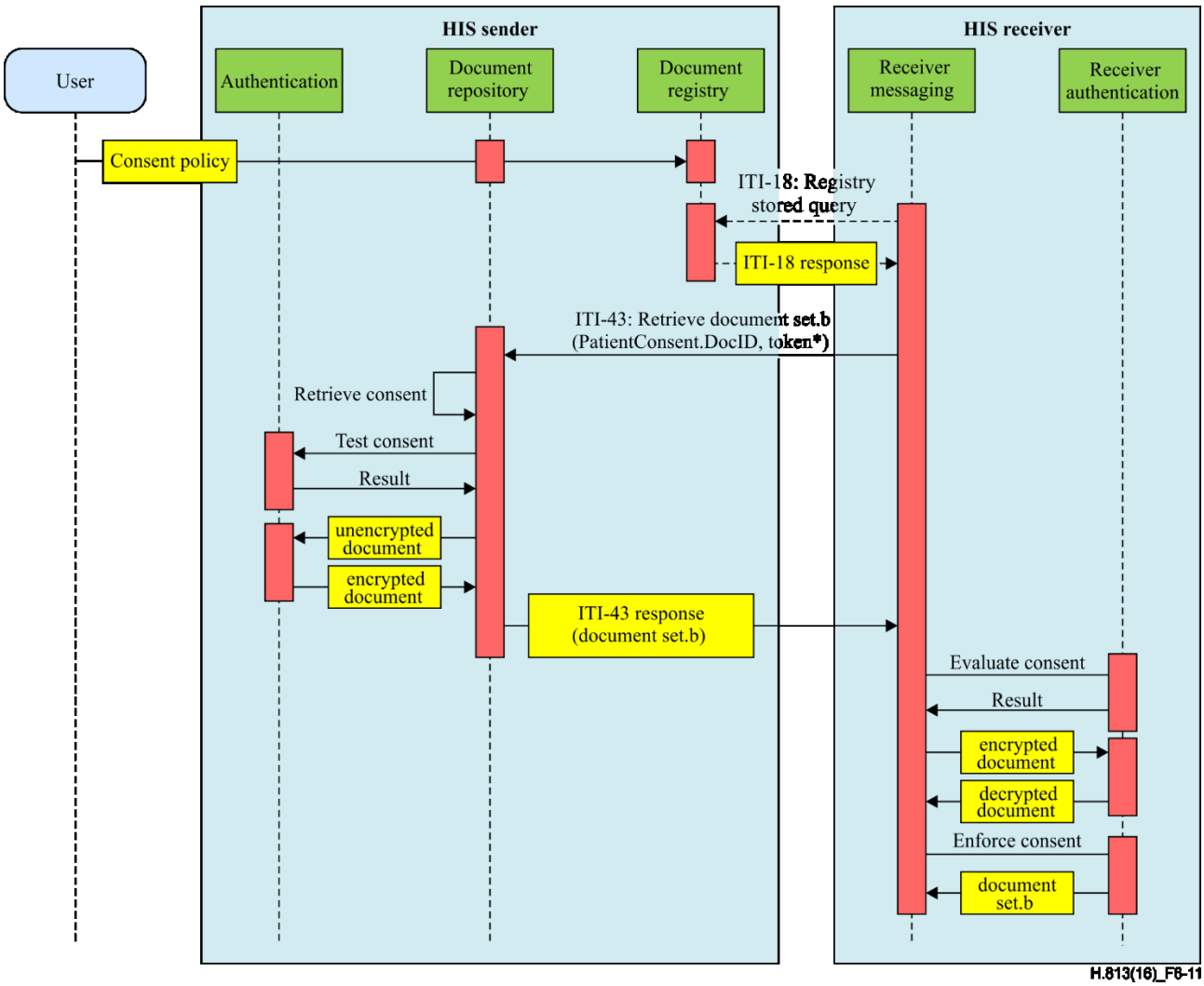

Figure 6-11 – Request-response interaction to obtain encrypted PHMR document along with consent document using IHE XDS at HIS-IF[1]

6.1.10 Delivery of PHMR data via ONC DIRECT

Guidance for implementations that elect to deliver CDG-compliant data from PHDs while meeting the United States' ONC's Meaningful Use requirements is found in clause V.1.

6.1.11 Certified capability classes

Table 6-1 shows the HIS certified capability classes defined for the HIS-IF interface design guidelines. At this time, the certification programme described in [ITU-T H.810] only provides certification for software components implementing HIS sender functionality. In contrast to the PHD interface, the HIS sender certification can just apply to a software implementation and does not require integration into an entire system.

NOTE – HIS capability classes and respective guidelines for national and regional systems can be found in Appendix V.

1 The grey items have already been specified in a previous version of the CDG.

Table 6-1 – HIS capability classes

Capability classes	Network messaging
HIS sender– Direct Communication	Yes
HIS receiver – Direct Communication	Not certified
HIS sender – Indirect Communication	Yes
HIS receiver – Indirect Communication	Not certified
HIS sender– ONC_DIRECT	Yes
HIS receiver– ONC_DIRECT	Not Certified
Non-repudiation Enabled HIS sender	Yes
Non-repudiation Enabled HIS receiver	Not certified
Consent Enabled HIS sender- XDR	Yes
Consent Enabled HIS receiver – XDR	Not certified
Consent Enabled HIS sender- XDS.b	Yes
Consent Enabled HIS receiver – XDS.b	Not certified

Certification of HIS capability classes are shown in Table 6-2. Capability classes are referenced even though receivers on the HIS interface are not currently certified (see clause 0.5), they can certainly be implemented by adhering to the appropriate guidelines (clause numbers) indicated in Table 6-2.

Table 6-2 – Guidelines for HIS capability classes

Capability classes	Relevant guidelines
HIS receiver – Direct Communication	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.1
HIS sender – Direct Communication	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.1
HIS receiver – Indirect Communication	6.2.2.2, 6.2.3.2, 6.2.3.3, 6.2.4, 6.2.5.2
HIS sender – Indirect Communication	6.2.2.2, 6.2.3.2, 6.2.3.3, 6.2.4, 6.2.5.2
HIS receiver - ONC_DIRECT	6.2.2.2, 6.2.3.2, 6.2.3.3, 6.2.4, 6.2.5.2
HIS sender - ONC_DIRECT	6.2.2.2, 6.2.3.2, 6.2.3.3, 6.2.4, 6.2.5.2
Non-repudiation Enabled HIS sender	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.3
Non-repudiation Enabled HIS receiver	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.1, Table 6-16
Consent Enabled HIS sender – XDR	6.2.2.1**,** 6.2.3.1**,** 6.2.3.3, 6.2.4, 6.2.5.1, Table 6-17, Table 6-21
Consent Enabled HIS receiver – XDR	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.1, Table 6-18, Table 6-22
Consent Enabled HIS sender – XDS.b	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.1, Table 6-23
Consent Enabled HIS receiver – XDS.b	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.1, Table 6-20, Table 6-24

6.2 Design guidelines

6.2.1 Introduction

The following clauses detail the specific rules, restrictions and guidelines for the Continua HIS interface.

In these guidelines, the HIS sender refers to a Continua HIS-IF client component and the HIS receiver refers to a Continua HIS-IF service component. The component naming was preserved for clarity.

6.2.2 Messaging infrastructure and transport guidelines

6.2.2.1 Requirements for direct communications via XDR

Table 6-3 – Requirements for HIS transport using XDR

Name	Description	Comments
HIS_Message_Infrastructure_ Profile	Continua HIS senders and receivers **shall** use the IHE XDR profile, for the transfer of messages between the HIS sender and HIS receiver	
HIS_Message_Infrastructure_ Protocol	Continua HIS senders and receivers **shall** use HTTP and SOAP 1.2 for Internet connectivity	
HIS_Message_Infrastructure_Init_ Connection	A Continua HIS sender **shall** initiate the connection to the HIS receiver	
HIS_Message_Infrastructure_ Internet	Continua HIS receivers **shall** be reachable from their HIS senders. Therefore, the HIS receiver either **shall** be on the same secure network as the HIS sender or **shall** be on a network connected to the HIS senders network across a secure connection or **shall** be Internet-facing (i.e., reachable from the Internet)	
HIS_Message_Infrastructure_ Sender_Topology	Continua HIS senders **shall** connect to one or multiple HIS receivers, sending only the relevant messages to each	This does not require connecting to multiple HIS receivers at the same time
HIS_Message_Infrastructure_ Receiver_Topology	Continua HIS receivers **shall** be able to receive messages from multiple HIS senders concurrently	
HIS_Messaging_Infrastructure_ Transport_Mode_Supported	Continua HIS senders and receivers **shall** utilize the XDR "on-line" mode of operation	The "on-line" mode is the v1 methodology
HIS_Messaging_Infrastructure_ Transport_Mode_Not_Supported	Continua HIS senders and receivers **shall not** utilize the XDR "off-line" mode of operation	The "off-line" mode is not supported for the v1 HIS interface

6.2.2.2 Requirements for indirect communications via XDM

Table 6-4 – Requirements for HIS transport using XDM

Name	Description	Comments
HIS_Indirect_Message_ Infrastructure_Profile	Continua HIS indirect communication senders and receivers **shall** implement the IHE XDM integration profile, for the indirect transfer of messages between the HIS sender and HIS receiver	
HIS_Indirect_Message_ Infrastructure_Protocol	Continua HIS senders and receivers **shall** implement the "ZIP over Email transport" option	
HIS_Indirect_Message_ Infrastructure_Privacy	Continua HIS senders and receivers **should** implement the "Basic Patient Privacy Enforcement" option	
HIS_Indirect_Message_ Infrastructure_Response	Continua HIS senders and receivers **may** implement the "Zip over Email Response" option	
HIS_Indirect_Message_ Infrastructure_Init_Connection	A Continua HIS sender **shall** initiate the communication with the HIS receiver	
HIS_Indirect_Message_ Infrastructure_Sender_Topology	Continua HIS senders **shall** communicate with one or multiple HIS receivers, sending only the relevant messages to each	This allows, but does not require, communicating with multiple HIS receivers at the same time

6.2.3 Messaging guidelines

6.2.3.1 Messaging guidelines for direct communications via XDR

Table 6-5 – General messaging guidelines

Name	Description	Comments
HIS_Messaging_Document_ Source_Standard	Continua HIS senders **shall** implement the document source actor of the IHE cross-enterprise document reliable interchange (XDR) profile for sending PHMR data	Primary v1 messaging/transport is based on IHE XDR profile and its referenced standards
HIS_Messaging_Document_ Recipient_Standard	Continua HIS receivers **shall** implement the document recipient actor of the IHE cross-enterprise document reliable interchange (XDR) profile for receiving PHMR data	Primary v1 messaging/transport is based on IHE XDR profile and its referenced standards
HIS_Messaging_Mode_Supported	Continua HIS senders and receivers **shall** utilize the XDR "on-line" mode of operation	The "on-line" mode is the methodology

Table 6-5 – General messaging guidelines

Name	Description	Comments
HIS_Messaging_Mode_Not_ Supported	Continua HIS senders and receivers **shall not** utilize the XDR "off-line" mode of operation	The "off-line" mode is not supported for the HIS interface
HIS_Messaging_Transport_ Exclusivity	Continua HIS senders and receivers **shall** utilize the transport mechanisms as defined in the XDR profile for all PHMR exchanges	
HIS_Messaging_Message_Scope	The Continua HIS sender application **should not** include information that is not present within the PHMR	This requirement is necessary since the primary usage of message is designed to only transmit PHMR data
HIS_Messaging_Meta_Data	The Continua HIS sender XDR meta-data **shall** be consistent with the included PHMR and its attachments	This is to ensure that any preprocessing based on the XDR meta-data is consistent with the PHMR payload. Of primary concern are the patient ID, the document ID and the originator ID
HIS_Messaging_Atomic_ Transaction	The Continua HIS sender and receiver exchange of the PHMR document transaction **shall** be atomic in that it may only succeed or be "rolled back" in its entirety if it fails	The state and condition of both the sender and the receiver must be maintained in a consistent manner regardless of the success of the exchange. This also means that this transaction is complete and not dependent on another transaction to send the intended data

6.2.3.2 Messaging guidelines for indirect communications via XDM

Table 6-6 – General messaging guidelines

Name	Description	Comments
HIS_Indirect_Message_Sender	The Continua HIS sender **shall** implement the portable media creator actor of the XDM profile	
HIS_Indirect_Message_Receiver	The Continua HIS receiver **shall** implement the portable media importer actor of the XDM profile	
HIS_Indirect_Messaging_ Document_Source_Standard	Continua HIS indirect communication senders **shall** implement the portable media creator of the cross-enterprise document media interchange (XDM) integration profile for	

Table 6-6 – General messaging guidelines

Name	Description	Comments
	sending PHMR data	
HIS_Indirect_Messaging_ Message_Scope_One_Report	The Continua HIS sender **shall** include exactly one submission set, including one PHMR document and associated metadata in the "Zip over Email" attachment	XDM allows for multiple documents and multiple patients to be sent. The CDG further restrains this to one PHMR document on one patient, with all related attachments
HIS_Indirect_Messaging_ Message_Scope	The contents of the submission set sent by the Continua HIS sender **shall** be related to the same patient	The XDM distribute document set on media transaction does not require that all the submission sets included in the media are relative to the same patient
HIS_Indirect_Messaging_ Document_Source_Directory_ Structure	The Continua HIS sender **shall** name the submission set directory that includes PHMR "SUBSET01"	
HIS_Indirect_Messaging_ Attachment_Scope_Allowed_ Content	The Continua HIS sender application **shall** include in the submission set ZIP file only the information that is relevant to the information within the PHMR	This requirement is necessary since the primary usage of the message is designed to only transmit PHMR data
HIS_Indirect_Messaging_ Message_Scope_Allowed_Content	The Continua HIS sender **shall** only include in the submission set files and directories that are required to transfer the submission set containing the PHMR and optional XML style sheet used to render the PHMR	There should not be contents that the HIS receiver would have to ignore. Especially, the attachment shall not include any executable files
HIS_Indirect_Messaging_ Message_Scope_Restricted_ Content	The Continua HIS sender **shall not** include in the submission set executable files and files that are configured to start automatically	Security related (executable files are allowed by XDM) Even when the PHMR would reference such a file and thus it would be allowed in the submission set –this is restricted and shall not be submitted
HIS_Indirect_Messaging_Meta_ Data	The Continua HIS sender XDM meta-data **shall** be consistent with the included PHMR and its attachments	This is to ensure that any preprocessing based on the XDM meta-data is consistent with the PHMR payload. Of primary concern are the patient ID, the document ID and the originator ID
HIS_Indirect_Messaging_Meta_ Data_Compatibility	The Continua HIS indirect sender XDM **shall** include all information in the XDM meta data that is required by the HIS direct sender XDR	This means Register Document Set-b [ITI-42] metadata as required by the XDR specification in [IHE ITI TFS XDR].

Table 6-6 – General messaging guidelines

Name	Description	Comments
		The XDM would allow also the Register Document Set [ITI-14] of [IHE ITI TFS XDR], which may not be XDR compatible
HIS_Indirect_Messaging_Atomic_ Transaction	The Continua HIS sender and receiver exchange of the PHMR document transaction **shall** be atomic in that the included PHMR is complete and that none of the content relies on content from other messages in order to be understood	
HIS_Indirect_Message_ Infrastructure_Internet	A Continua HIS sender **shall** either export the PHMR "Zip over E-Mail" media as a one ZIP file or create an e-mail with the PHMR attached as a ZIP file using internal e-mail processing	This gives the sender flexibility to either create the e-mail with the attachment or export the ZIP package for manual attachment to an e-mail
HIS_Indirect_Message_ Infrastructure_Internet_Email	If the Continua HIS sender exports the "Zip over E-Mail" it **shall** include the PHMR in the media that comply with the requirements of the XDM media format as a single-file ZIP package that can be attached to an e-mail message	
HIS_Indirect_Message_ Infrastructure_Internet_ Attachment	If the Continua HIS sender creates an e-mail with the XDM submission set attached, the submission set **shall** contain the PHMR in the prescribed format	
HIS_Indirect_Message_ Infrastructure_Manual_Auditing	If a Continua HIS sender is used by a person manually creating the XDM "Zip over E-Mail" media, the HIS sender **shall** maintain an audit log of PHMR documents exported for delivery that adheres to the IHE ATNA Auditing related clauses as defined for XDM	Auditing ATNA "Export" is required for the XDM. See [IHE ITI TF-1] for more details on ATNA.The manual e-mail option could skip the auditing step. This would not be a compliant or complete implementation
HIS_Indirect_Messaging_ Infrastructure_Acknowledgement_ Receiver	Continua HIS receivers **may** send the HIS sender an indirect acknowledgement that the HIS sender message was received and processed using the "Zip over Email Response" option	This corresponds to the protocol option "Zip over Email Response". For XDM, acknowledgement is recommended, but never required
HIS_Indirect_Messaging_ Infrastructure_Acknowledgement_ Sender	If the "Zip over Email Response" option is used the Continua HIS senders **should** send the document ID in the e-mail subject line in addition to the required subject	The document ID format is ASCII text. There is no failure handling mechanism beyond what standard e-mail provides and

Table 6-6 – General messaging guidelines

Name	Description	Comments
	XDM/1.0/DDM in the format: XDM/1.0/DDM/DocumentID	no consistent time-out standard is possible due to variability of how people read e-mail. Any concerns over whether or not a message was received should be handled manually
HIS_Indirect_Messaging_ Infrastructure_Acknowledgement_ Subject	If the Continua HIS receiver sends indirect acknowledgement using the "Zip over Email Response" option, the response message **should** include the subject line of the original e-mail message	The acknowledgment e-mail subject should contain the exact contents of the original e-mail's subject, prefixed by "RE:" (the way typical e-mail replies are handled) NOTE – An e-mail return receipt only assures that the e-mail was correct, not that the attachment was readable or successfully imported. These require a further acknowledgement from the importer

6.2.3.3 Messaging guidelines applicable to both direct and indirect communications

Table 6-7 – PHMR attachments guidelines

Name	Description	Comments
HIS_PHMR_Attachments_Attachment_ Completeness	Continua HIS senders **shall** communicate all attachments referenced or contained in the PHMR document	
HIS_PHMR_Attachments_Message_ Completeness	Continua HIS senders **shall** communicate all attachments specified in the PHMR in the same message	

Table 6-8 – Patient identity mapping guidelines

Name	Description	Comments
HIS_Patient_Identity_Mapping	Continua HIS senders **shall** implement the patient identity source actor of IHE ITI-44: Patient Identity Feed HL7 V3 in order to submit new patient identifiers to the HIS receiver or third party exchanges	
HIS_Registration	Continua HIS senders **may** implement the patient identity source actor of IHE ITI-44: Patient Identity Feed HL7 V3 in order to submit a new device registration to the HIS receiver or third party exchanges	

Table 6-8 – Patient identity mapping guidelines

Name	Description	Comments
HIS_Patient_Identity_Query	Continua HIS senders and receivers **may** implement the patient identifier cross-reference consumer actor of the IHE ITI-45: PIXV3 Query transaction in order to map between their local identifiers and the identifiers used for exchange	
HIS_Patient_Demographics_Query	Continua HIS receivers **may** implement the patient demographics consumer actor of the IHE ITI-47: Patient Demographics Query HL7 V3 transaction, using the patient name and demographics in order to correlate the record with its own local identifiers	

Table 6-9 – Quality of service guidelines

Name	Description	Comments
HIS_Transport_QoS_Best.Veryhigh	Continua HIS senders and receivers **shall** implement the Continua *best.veryhigh* QoS bin using TCP as specified in clause 2, Basic functionality of [IETF RFC 4614]: 1. IETF RFC 793 2. IETF RFC 1122 3. IETF RFC 2460 4. IETF RFC 2581 5. IETF RFC 2873 6. IETF RFC 2988	

6.2.4 Data guidelines

Table 6-10 – General data format guidelines

Name	Description	Comments
HIS_Data_Standard	Continua HIS sender and receiver data format **shall** comply with [HL7 CDA-PHMR]	
HIS_Data_Subject_ Identity	Continua HIS senders **shall** uniquely identify a patient within for the HIS receiver domain in the `/ClinicalDocument/recordTarget` element	Assuring that patient ID is understood in the receiver
HIS_Data_Receiver_ Identity	A Continua HIS sender **shall** identify a HIS receiver within the `/ClinicalDocument/informationRecipient` element	

Table 6-10 – General data format guidelines

Name	Description	Comments
HIS_Data_Receiver_As_ Custodian	A Continua HIS sender **shall** specify `/ClinicalDocument/custodian` element	The receiver becomes a custodian of the document (Element Required in CDA)
HIS_Data_Author_ Organization_Identity	Continua HIS senders **shall** identify the organization associated with HIS sender as the author of the PHMR document in the `/ClinicalDocument/author/assignedAuthor/representedOrganization` element	
HIS_Data_Authoring_ PHD_Identity	Continua HIS senders **should** identify the personal health gateway/ Health & Fitness service in the role of HIS sender in the `/ClinicalDocument/author/assignedAuthor/assignedAuthoringDevice` element	
HIS_Data_Document_ Identity	Continua HIS senders **shall** assign the document unique identifier in the `/ClinicalDocument/id` element according to guidelines for HL7 CDA documents [HL7 CDA]	CDA specification uses II (instance identifier) composed of a root and extension
HIS_Data_ Measurement_Units	Continua HIS sender data format **shall** interpret the UCUM units of measure according to mapping in Table III.1, Table III.2 and Table III.3.	
HIS_Data_Original_ Data_Authoring_PHD_ Identity	For all original data, Continua HIS senders **shall** include a reference to originating personal health device identified by unique device identifier	To comply with the recommendation in [b-CHA UI]. Continua PHDs use EUI-64 device identifier
HIS_Data_Processed_ Data_Author_Identity	For processed data, Continua HIS senders **should** include a reference to the PHD that processed the data	Recommended by [b-CHA UI] NOTE – This may propagate up to the authoring PHD as defined in HIS_Data_ authoring_PHD_ _identity
HIS_Data_Coding_ Snomed	Continua HIS sender **shall** use SNOMED CT coding for device data as identified in Table III.1, Table III.2 and Table III.3.	The effort was made to map all clinical data types and most events / alerts into SNOMED CT
HIS_Data_Coding_Mdc	Continua HIS sender **shall** use original MDC coding for device data that does not have identified SNOMED CT code in Table III.1, Table III.2 and Table III.3.	Some events and alerts

Table 6-10 – General data format guidelines

Name	Description	Comments
HIS_Data_Coding_ Unencoded_Bitmaps	Continua HIS sender **should** use local coding agreed upon with HIS receiver for device data that does not have either identified MDC or SNOMED CT code in Table III.1, Table III.2 and Table III.3.	For example bitmap coded device data, manufacturer-specific error codes. HIS sender may also choose not to send such data. HIS receiver must gracefully handle cases when the coding is not supported
HIS_Data_Coding_ Legacy_And_Manual_ Data	Continua HIS sender **shall** transfer data from PHDs that do not provide MDC codes and manually entered data using SNOMED CT coding and if available using codes in the SNOMED-CT mapping in Table III.1, Table III.2 and Table III.3.	To allow data from Personal Health Devices that do not provide MDC codes still to be transferred using SNOMED CT as if they were manual entries

6.2.4.1 Data guidelines for PHDs related to medication delivery

Table 6-11 – General medication delivery guidelines

Name	Description	Comments
HIS_Data_Medication_ Section	If medication delivery data is communicated, the Continua HIS sender **shall** report the medication delivery in medications section (CCD templateId 2.16.840.1.113883.10.20.1.8)	The HL7 PHMR report [HL7 CDA-PHMR] covers the vital signs and results. This section adds the medication delivery guidelines. Based on HL7 PHMR: This section if present SHALL conform to all the constraints specified in CCD
HIS_Data_Medication_ Exclusive_Section	If Continua HIS sender is only submitting medication data and not submitting data in the vital signs nor the result sections, the HIS sender **shall** include an empty "Vital Signs" section that contains a text element noting this fact	To comply with the HL7 PHMRguideline [HL7 CDA-PHMR].
HIS_Data_Medication_ Substance_ Administration	The Continua HIS sender **shall** represent the medication delivery activity as the SubstanceAdministration	CCD Section 3.9.2.1.1 Medication activity [HL7 CDA-CCD].
HIS_Data_Medication_ Substance_ Administration_Event	In the Continua HIS sender submitted data the value for "SubstanceAdministration / @moodCode" in a medication activity **shall** be "EVN"	

Table 6-11 – General medication delivery guidelines

Name	Description	Comments
HIS_Data_Medication_ Consumable	In the Continua HIS sender submitted data the medication definition **shall** be implemented as `SubstanceAdministration /consumable`, the target of which is a product template in accordance with the PHMR specification	To comply with the CCD template. The coding system shall be based on regional needs of the HIS sender and receiver. There is no universal medication coding
HIS_Data_Medication_ Substance_ Administration_Code	In the Continua HIS sender submitted data the value for the `SubstanceAdministration /code` **shall** contain the original MDC code if code is reported from the device	
HIS_Data_Medication_ PHD_Specific_ Attributes	The Continua HIS sender **shall** transmit a PHD-specific attribute with no semantic CDA equivalent, as an entryRelationship containing an observation where observation/code contains the attribute type and observation/value contains the attribute value	An example is fast bolus delivery vs. slow bolus delivery. An attribute "fast" can be added using an observation linked via entryRelationship to a Substance administration
HIS_Data_Medication_ Originating_PHD_ Specification	The Continua HIS sender **shall** represent the medication delivery PHD as the participant element of the SubstanceAdministration conforming to the constraints of a PHMR product instance reference	PHMR IG: Chapter 3.5.4 of PHMR Product Instance Reference Also to comply with guideline: HIS_Data_original_data_authoring_PHD_identity [HL7 CDA-PHMR]

Table 6-12 – Adherence monitor specific guidelines (separate from general medication guidelines)

Name	Description	Comments
HIS_Data_Coding_Dosage_ Dispensed	Continua HIS sender and receiver data format **shall** contain SubstanceAdministration/effectiveTime, SubstanceAdministration/doseQuantity, SubstanceAdministration/consumable and SubstanceAdministration/routeCode elements at a minimum	
HIS_Data_Medication_ Delivery_Route	In the Continua HIS sender submitted data, the value for "SubstanceAdministration / routeCode" in a medication activity **shall** be one of the delivery routes from the HL7 RouteOfAdministration (2.16.840.1.113883.5.112) code system	For example, ingestion by swallowing orally is "PO" (internalId: 14735)
HIS_Data_Coding_Dosages_ Scheduled_(Regimen)	Continua HIS sender and receiver data format **shall** use an HL7 substanceAdministration entry with a classCode of "SBADM" and a moodCode of "INT" for encoding dosage dispensed events in the PHRM	Restriction on the CCD template
HIS_Data_Coding_Question_ Responses	Continua HIS sender and receiver data format **shall** comply with [HL7 CDA_R2_QA] (universal realm) for encoding question and response events in the PHRM	
HIS_Data_Coding_Question_ Responses_Code_Systems	Continua HIS sender and receiver Observation/code **may** be selected from LOINC codeSystem 2.16.840.1.113883.6.1, or SNOMED CT codeSystem 2.16.840.1.113883.6.96, or International Classification of Functioning, Disability and Health (ICF) codeSystem 2.16.840.1.113883.6.254 and/or a local code system that identifies the question/response in a manner that is agreed to by the collaborating parties	Preference is for reuse of existing question/response code schemes, but allowance is made for rapid expansion and local schemes. This guideline is relaxed with the Framework for Questionnaire Assessments specification

6.2.5 Security guidelines

6.2.5.1 Security guidelines for direct communications via XDR

Table 6-13 – General security guidelines

Name	Description	Comments
HIS_Security_Communication	Continua HIS senders and receivers **shall** ensure all direct communication is done via specified XDR secure mechanism	
HIS_Security_Authentication	Continua HIS senders and receivers **shall** use a prior agreed upon XDR mechanism to ensure authentication	
HIS_Security_Auditing1	Continua HIS senders and receivers **shall** implement and adhere to audit trail and node identification (ATNA) clauses of the XDR profile	
HIS_Security_Cipher	Continua HIS senders and receivers **should** use an encryption cipher suite of TLS_RSA_WITH_AES_128_CBC_SHA	

6.2.5.2 Security guidelines for indirect communications via XDM

Table 6-14 – General security guidelines

Name	Description	Comments
HIS_Security_Communication	The secure communication between Continua sender and receiver is guided by: HIS_Indirect_Message_Infrastructure_privacy guideline (see Table 6-4)	
HIS_Security_Authentication	Continua HIS senders and receivers **shall** use a prior agreed upon mechanism to ensure authentication	Authentication is of both sender and receiver
HIS_Security_Auditing	The auditing of interaction between Continua HIS sender and receiver is guided by: HIS_Indirect_Message_Infrastructure_manual_auditing guideline (see Table 6-6)	

6.2.5.3 Security guidelines for integrity, data origin authentication and non-repudiation

NOTE – Other guidelines that are applicable for the non-repudiation enabled HIS sender and receiver are mentioned in Table 6-2.

Table 6-15 – Integrity, data origin authentication and non-repudiation HIS sender guidelines

Name	Description	Comments
HIS_Sender_Sign	Non-repudiation enabled HIS sender **shall** sign PHMR document(s) according to IHE document digital signature content profile	
HIS_Sender_Signature_ Algorithm	Non-repudiation enabled HIS sender **shall** use RSA-SHA256 as the signature algorithm	[FIPS PUB 180-4] (using the cyphers compatible with [b-FIPS PUB 180-2])

Table 6-16 – Integrity, data origin authentication and non-repudiation HIS receiver guidelines

Name	Description	Comments
HIS_Receiver_Verify	Non-repudiation enabled HIS receiver **shall** verify PHMR document(s) according to the IHE documents digital signature content profile and only accept documents that pass the signature verification	
HIS_Receiver_Verification_ Algorithm	Non-repudiation enabled HIS receiver **shall** support RSA-SHA256 signature algorithm	

6.2.6 Consent management guidelines

NOTE – Other guidelines that are applicable for the consent enabled HIS sender and receiver are mentioned in Table 6-2.

6.2.6.1 Security guidelines for consent management

Table 6-17 – Consent management guidelines for consent enabled HIS sender via XDR

Name	Description	Comments
HIS_Sender_Consent_Document_ Format_XDR	Consent enabled HIS sender **shall** comply with [HL7 CDA IG] to represent patient consent in a consent document	
HIS_Sender_Consent_Clinical_ Document(s)_ ConfidentialityCode_XDR	Consent enabled HIS sender **shall** set the confidentiality code value to "R" in the header of the PHMR document	
HIS_Sender_Consent_Clinical_ Document(s)_Association_XDR	To associate PHMR documents(s) with the patient consent document, consent enabled HIS sender **shall** use the translation element of the confidentiality code system as defined in Table I.8	Consult Table I-6 for the elements of the confidentiality code system Consult Table I.7 for the elements of the Continua Consent Directive code system Consult Table I.9 for the assigned OIDs

Table 6-17 – Consent management guidelines for consent enabled HIS sender via XDR

Name	Description	Comments
HIS_Sender_Consent_Transport_ XDR	Consent enabled HIS sender **shall** use IHE XDR profile to send a consent document along with PHMR document(s)	The consent document and PHMR document(s) could be sent in the same submission set of the ITI-41 Provider and Register Document Set.b transaction
HIS_Sender_Consent_ Personlization_XDR	Consent enabled HIS sender **may** personalize permissions in the consent document based on the identity or roles of the requester and/or jurisdictional and organizational security policies	The roles are indicated by an SAML attribute token. An example of personalization is the creation of a modified consent document with the permissions and authorizations based on the role of requester (e.g., doctor or nurse)
HIS_Sender_Audit_log_XDR	Consent snabled HIS sender **should** create audit events and send to audit repository using IHE ATNA in case of the occurrence of the following events: Release of PHMR document(s) Release of consent document(s)	IHE ATNA is covered by HIS security guideline named as: HIS_Security_Auditing1

Table 6-18 – Consent management guidelines for consent enabled HIS receiver via XDR

Name	Description	Comments
HIS_Receiver_Consent_Format_ XDR	Consent enabled HIS receiver **shall** be able to receive, interpret and enforce HL7 CDA R2 consent directive patient consent document(s) [HL7 CDA IG]	
HIS_Receiver_Consent_ Transport_XDR	Consent enabled HIS receiver **shall** use the IHE XDR profile to receive a consent document	The consent document could be received through the ITI-41 Provider and Register Document Set.b transaction alone or with the PHMR document(s) in the same submission set

Table 6-19 – Consent management guidelines for consent enabled HIS sender via XDS.b

Name	Description	Comments
HIS_Sender_Consent_ Document_Format_XDS.b	Consent enabled HIS sender **shall** comply with [HL7 CDA IG] to represent patient consent in a consent document	
HIS_Sender_Source_Actor	Consent enabled HIS sender **shall** implement the document source actor of the IHE XDS.b profile	The source actor consequently supports the ITI-41 Provider and Register Document Set.b transaction
HIS_Sender_Repository_ Actor	Consent enabled HIS sender **shall** implement the document repository actor of the IHE XDS.b profile	
HIS_Sender_Registry_ Actor	Consent enabled HIS sender **shall** implement the document registry actor of the IHE XDS.b profile	Enables query and lookup of PHMR and consent documents through IHE ITI-18 registry stored query transaction
HIS_Sender_Consent_ Clinical_Document(s)_ ConfidentialityCode_XDS.b	Consent enabled HIS sender **shall** set the confidentiality code value to "R" in the header of the PHMR document	
HIS_Sender_Consent_ Clinical_Document(s)_ Association_XDS.b	To associate PHMR documents(s) with the patient consent document, consent enabled HIS sender **shall** use the translation element of the confidentiality code system as defined in Table I.8	Consult Table I-6 for the elements of the confidentiality code system Consult Table I.7 for the Continua Consent Directive code system Consult Table I.9 for the assigned OIDs
HIS_Sender_Publishing_ Repository	Consent enabled HIS sender **shall** make consent documents available in the document repository	See also HIS_Sender_Repository_Actor guideline
HIS_Sender_Publishing_ Registry	Consent enabled HIS sender **shall** publish the XDS metadata for the published consent documents in the document registry	See also HIS_Sender_Registry_Actor guideline. This enables the search of the PHMR documents for a specific patient
HIS_Sender_Authentication	Consent enabled HIS sender **shall** authenticate the document consumer using the token as specified by IHE XUA in the request message	It facilitates the authentication of the user rather than the node and enables the personalization of consent documents. The authentication functionality is part of the document repository actor implemented on the HIS sender. IHE XUA profile (ITI-18 Provide X-User Assertion) uses SAML token for authentication

Table 6-19 – Consent management guidelines for consent enabled HIS sender via XDS.b

Name	Description	Comments
HIS_Sender_Attribute_ Authentication_	Consent enabled HIS sender **may** authenticate the document consumer actor based on attribute token as specified by IHE XUA++ profile	This is to support roles and role based access control (RBAC) IHE XUA++ profile uses SAML attribute token. XUA++ refers to OASIS XSPA profile of SAML for healthcare
HIS_Sender_Response_ Successful	Consent enabled HIS sender **shall** return patient consent document after successful authentication of the document consumer and successful verification that sending the document satisfies the patient consent policies	This is the positive response of the document repository actor after the reception of the retrieve document request according to ITI-43 Retrieve Document Set.b transaction
HIS_Sender_Response_Fail	Consent enabled HIS sender **shall** return a failure message if the document consumer fails to authenticate or document consumer fails to satisfy patient consent policies	This is a negative response from the document repository actor after the reception of the retrieve document request according to ITI-43 Retrieve Document Set.b transaction
HIS_Sender_Consent_ Personlization_XDS.b	Consent enabled HIS sender **may** personalize permissions in the consent document based on the identity or roles of the requester and/or jurisdictional and organizational security policies	The roles are indicated by the SAML attribute token. An example of personalization is the creation of a modified consent document with the permissions and authorizations based on the role of requester (e.g., doctor or nurse)
HIS_Sender_Audit_log_ XDS.b	Consent enabled HIS sender **should** create audit events and send to audit repository using IHE ATNA in case of the occurrence of the following events: Successful authentication Authentication failure Release of PHMR document(s) Release of consent document(s)	IHE ATNA is covered by HIS security guideline named as: HIS_Security_Auditing1

Table 6-20 – Consent management guidelines for consent enabled HIS receiver via XDS.b

Name	Description	Comments
HIS_Receiver_Consent_Format_ XDS.b	Consent enabled HIS receiver **shall** be able to receive, interpret and enforce [HL7 CDA IG] patient consent document(s)	
HIS_Receiver_Consumer_Actor	Consent enabled HIS receiver **shall** implement document consumer actor of IHE XDS profile for retrieving consent documents from the document repository of the Continua HIS sender	ITI-43 Retrieve Document Set.b a transaction is used to retrieve the document set from the repository
HIS_Receiver_Registry_Query	Consent enabled HIS receiver **shall** use ITI-18 Registry Stored Query transaction to retrieve unique identifier(s) of a patient consent document	Use if the identifier and URL of the repository are unknown
HIS_Receiver_Authentication	Consent enabled HIS receiver **shall** authenticate to the Continua HIS sender using a token as specified by IHE XUA (cross-enterprise user assertion) profile	Token is sent in ITI-43 Retrieve Document Request for PHMR and/or consent document. The token is placed in the SOAP header. IHE XUA profile uses SAML token for authentication
HIS_Receiver_Attribute_ Authentication	Consent enabled HIS receiver **may** authenticate to the Continua HIS sender using the attribute token as specified by IHE XUA++ profile	This is to realize role based access control IHE XUA++ uses SAML Attribute token. IHE XUA++ refers to the OASIS XSPA profile of SAML for healthcare

6.2.7 Consent enforcement design guidelines

NOTE – Other guidelines that are applicable for the consent enabled HIS sender and receiver are mentioned in Table 6-2.

6.2.7.1 Security guidelines for consent enforcement

Table 6-21 – Consent enforcement guidelines for consent enabled HIS sender via XDR

Name	Description	Comments
HIS_Sender_Content_Encryption_ Actor_XDR	Consent enabled HIS sender **shall** encrypt PHMR document(s) in compliance with IHE document encryption (DEN) profile	IHE DEN is based on cryptographic message syntax (CMS) standard
HIS_Sender_Content_Encryption_ Algorithm_XDR	Consent enabled HIS sender **shall** use AES-128 CBC for encryption of the document(s)	The algorithm used is identified through the ContentEncryptionAlgorithmIdentifier in CMS
HIS_Sender_Encryption_ Recipient_Binding_PKI_XDR	Consent enabled HIS sender **shall** implement PKI based key management method from IHE DEN profile	PKI based content key management method uses KeyTransRecipientInfo as CMS RecipientInfoType. This points to the public key or x.509 v3 certificate of the recipient
HIS_Sender_Encryption_ Recipient_Binding_Other_XDR	Consent enabled HIS sender **may** implement other key management methods from IHE DEN profile	

Table 6-22 – Consent enforcement guidelines for consent enabled HIS receiver via XDR

Name	Description	Comments
HIS_Receiver_Consent_ Evaluation_XDR	Consent enabled HIS receiver **shall** evaluate consent before decrypting the encrypted PHMR document(s)	E.g., determining that the recipient is using a document for the purpose authorized by the consent document and/or required infrastructure is available for the consent enforcement
HIS_Receiver_Content_ Decryption_Actor_XDR	Consent enabled HIS receiver **shall** comply with content consumer actor of IHE DEN profile to decrypt document(s)	
HIS_Sender_Encryption_ Recipient_Binding_XDR	Consent enabled HIS receiver **shall** support all key management methods specified by the IHE DEN profile	
HIS_Receiver_Content_ Decryption_Algorithm_XDR	Consent enabled HIS receiver **shall** use AES-128 CBC decryption algorithm	The algorithm used is identified through the ContentEncryptionAlgorithmIdentifier in CMS
HIS_Receiver_Consent_ Enforcement_XDR	Consent enabled HIS receiver **shall** enforce consent preferences expressed in the consent document	E.g., prevents further disclosure of the content to the unauthorized entities

Table 6-23 – Consent enforcement guidelines for consent enabled HIS sender via XDS.b

Name	Description	Comments
HIS_Sender_Publishing_PHMR_ Repository_XDS.b	Consent enabled HIS sender **shall** make PHMR document(s) available in the document repository	
HIS_Sender_Publishing_Registry_ XDS.b	Consent enabled HIS sender **shall** publish the XDS metadata for the published PHMR document(s) in the document registry	
HIS_Sender_Content_Encryption_ Actor_XDS.b	Consent enabled HIS sender **shall** encrypt PHMR document(s) in compliance with IHE DEN profile	
HIS_Sender_Response_Successful	Consent enabled HIS sender **shall** return encrypted PHMR document(s) after successful authentication of the document consumer and successful verification that sending the document satisfies the patient consent policies	The related consent management guidelines are: HIS_Sender_Authentication, HIS_Sender_Attribute_Authe ntication, HIS_Sender_Response_Succe ssful and HIS_Sender_Response_Fail
HIS_Sender_Content_Encryption_ Algorithm_XDS.b	Consent enabled HIS sender **shall** use AES-128 CBC for encryption of the PHMR document(s)	The algorithm used is identified through the ContentEncryptionAlgorithmI dentifier in CMS
HIS_Sender_Encryption_ Recipient_Binding_PKI_XDS.b	Consent enabled HIS sender **shall** implement a PKI based key management method from the IHE DEN profile	PKI based content key management method uses KeyTransRecipientInfo as CMS RecipientInfoType. This points to the public key or x.509 v3 certificate of the recipient
HIS_Sender_Encryption_ Recipient_Binding_Other_XDS.b	Consent enabled HIS sender **may** implement other key management methods from the IHE DEN profile	

Table 6-24 – Consent enforcement guidelines for consent enabled HIS receiver via XDS.b

Name	Description	Comments
HIS_Receiver_Registry_Query_ XDS.b	Consent enabled HIS receiver **shall** use ITI-18 Registry Stored Query transaction to retrieve unique identifier(s) of a patient PHMR document(s)	The ITI-18 has already been specified in the consent management guidelines. See the guidelines HIS_Sender_Registry_Actor and HIS_Receiver_Registry_Query
HIS_Receiver_Re_Query_XDS.b	Consent enabled HIS receiver **shall** use ITI-43 Retrieve Document Set.b transaction to retrieve PHMR document(s)	ITI-43 has already been specified in the consent management guidelines. See the guideline HIS_Receiver_Consumer_Actor
HIS_Receiver_Consent_ Evaluation_XDS.b	Consent enabled HIS receiver **shall** evaluate consent before decrypting an encrypted PHMR document	E.g., determining that the recipient is using the document for the purpose authorized by the consent document and/or required infrastructure is available for the consent enforcement
HIS_Receiver_Content_ Decryption_Actor_XDS.b	Consent enabled HIS receiver **shall** comply with content consumer actor of the IHE document encryption profile to decrypt PHMR document(s)	
HIS_Sender_Encryption_ Recipient_Binding_XDS.b	Consent enabled HIS receiver **shall** support all key management methods specified by the IHE DEN profile	
HIS_Receiver_Content_ Decryption_Algorithm_XDS.b	Consent enabled HIS receiver **shall** use AES-128 CBC decryption algorithm	
HIS_Receiver_Consent_ Enforcement_XDS.b	Consent enabled HIS receiver **shall** enforce the consent preferences expressed in the consent document	E.g., prevents further disclosure of the content to the unauthorized entities

Appendix I

Messaging implementation and technology

(This appendix does not form an integral part of this Recommendation.)

I.1 Overview

The XDR transaction (used for direct communication on the HIS interface) consists of the document source actor (HIS sender) transmitting a SOAP message to the document recipient actor (HIS receiver). Upon receipt, the document recipient actor replies by transmitting back an acknowledgement SOAP message.

For indirect HIS interface communication, XDM is used. XDM does not require the HIS receiver to send back an acknowledgement. However, an indirect, non-technical acknowledgement of each XDM communication is strongly recommended. Furthermore, in the case of auto-generated e-mail messages (where the HIS sender creates an e-mail message and attaches the ZIP file to it), it is strongly recommended that the subject of the message include a unique message identifier (not the patient ID) that can be included in the e-mail acknowledgement and identify which message is being acknowledged. Regardless of the media delivery method employed (e-mail, ftp, USB, CD-ROM, etc.), this non-technical acknowledgement **may** come in the form of an e-mail (or e-mail reply, if e-mail was the original media delivery method), telephone call or other method acceptable to both communicating partners. If the message is sent via e-mail, e-mail acknowledgement is preferred. The unique message identifier can be as simple as a counter that starts with 1 on the first XDM message ever sent and increments from there with each new XDM message from that XDM sender. It need not be unique across all XDM senders, only for that one XDM sender.

I.2 XDR and XDM metadata

The IHE profiles XDR and XDS organize their requirements based on concepts from the XDS family of profiles (of which XDR and XDM are members). Fundamentally, for the metadata, there are two primary pieces, the XDS submission set piece and the XDSDocumentEntry piece. The tables below show the HIS required entries for a conformant HIS transaction.

NOTE – While the profile discussions are in the terms below, when the actual SOAP envelope is constructed (for XDR messages); these terms are encoded in ebXML terms for electronic transfer.

References:

– Primary background is the IHE ITI TF-2 clause 4.1 [b-IHE ITI TF 2 R4] and IHE PCC working group mapping [b-IHE PCC TF 2]

– Implementation Guide for PHMR Release 1.0 [HL7 CDA-PHMR]

Table I.1 – Element requirement

Code	Meaning
R	Required
R2	Required if known
O	Optional
N	Not Allowed

Table I.2 – XDS submission set metadata

Element	Req.	HIS PHMR mapping	Comments
availabilityStatus	(O)		See comment in the XDS DocumentEntry table
author	(R2)	/ClinicalDocument/author	See comment in the XDS DocumentEntry table
authorInstitution	(R2)	/ClinicalDocument/author/assignedAuthor/ representedOrganization	
authorPerson	(O)	/ClinicalDocument/author/assignedAuthor/ assignedPerson	
authorRole	(R2)	/ClincicalDocument/author/participationFunction	
authorSpecialty	(R2)	/ClinicalDocument/author/assignedAuthor/code	
comments	(O)		
contentTypeCode	(R)		The value of this element can be any value agreed upon by the two transaction participants
contentTypeCodeDisplayName	(O)	"Subsequent evaluation" (R if contentTypeCode present)	The value of this element can be any value agreed upon by the two transaction participants
entryUUID	(R)	unique ID for submission set	
patientId	(R)	Mapped from /ClinicalDocument/recordTarget/ patientRole/id	
sourceId	(R)	Unique OID assigned to the system that is submitting the submission set	
submissionTime	(R)	Message submission time	
title	(O)	/ClinicalDocument/title	
uniqueId	(R)	/ClinicalDocument/id	

NOTE – For the HIS-IF, the submission set may only contain a single PHMR document.

Table I.3 – XDSDocumentEntry metadata

Element	Req.	HIS PHMR mapping	Comments
availabilityStatus	(O)		XDR and XDM are subsets of XDS that do not have Registry/Repository actors. Therefore, the requirement level is defined as "optional"
author	(R2)	/ClinicalDocument/author	Composed of sub-elements (defined below): – authorInstitution – authorPerson – authorRole – authorSpeciality
authorInstitution	(R2)	/ClinicalDocument/author/ assignedAuthor/ representedOrganization	
authorPerson	(R2)	/ClinicalDocument/author/ assignedAuthor/assignedPerson	
authorRole	(R2)	/ClinicalDocument/author/ assignedAuthor/code	
authorSpecialty	(R2)	/ClincicalDocument/author/ participationFunction	
classCode	(R)		The value of this element can be any value agreed upon by the two transaction participants
classCodeDisplayName	(O)		(R if classCode present) The value of this element can be any value agreed upon by the two transaction participants
Comments	(O)		
confidentialityCode	(R)	/ClinicalDocument/ confidentialityCode	
confidentialityCode DisplayName	(O)	/ClinicalDocument/ confidentialityCode (R if confidentialityCode present)	
creationTime	(R)	/ClinicalDocument/effectiveTime	
entryUUID	(R)	unique ID for documentEntry	
eventCodeList	(O)	/ClinicalDocument/ documentationOf/serviceEvent/ code	
eventCodeDisplay NameList	(O)	(R if eventCodeList present)	
formatCode	(R)	"urn:continua:phm:2008"	
formatCodeDisplay Name	(O)		
hash	(R)		

Table I.3 – XDSDocumentEntry metadata

Element	Req.	HIS PHMR mapping	Comments
healthcareFacilityTypeCode	(R)		The value of this element can be any value agreed upon by the two transaction participants
healthcareFacilityTypeCodeDisplayName	(R)		(R if healthcareFacilityTypeCode present) The value of this element can be any value agreed upon by the two transaction participants
intendedRecipient	(O)	/ClinicalDocument/ intendedRecipient	
languageCode	(R)	/ClinicalDocument/languageCode	
legalAuthenticator	(O)	/ClinicalDocument/ legalAuthenticator	Additional transformation is required as described in the mapping table of [b-IHE PCC TF 2]
mimeType	(R)	text/xml	
parentDocument	(N)		Optional encoding, may come from[2]/ClinicalDocument/relatedDocument/parentDocument
parentDocumentId	(N)		Optional encoding may come from /ClinicalDocument/relatedDocument/parentDocument/id
parentDocumentRelationship	(N)		Optional encoding may come from /ClinicalDocument/ relatedDocument/typeId
patientId	(R)	/ClinicalDocument/recordTarget/ patientRole/id	
practiceSettingCode	(R)		The value of this element can be any value agreed upon by the two transaction participants
practiceSettingCodeDisplayName	(R)		(R if practiceSettingCode present) The value of this element can be any value agreed upon by the two transaction participants
serviceStartTime	(O)	/ClinicalDocument/ documentationOf/serviceEvent/ effectiveTime/low	Contained in PHMR data

[2] What gets stored in the application may not be what gets sent. For example, version 1 is sent, version 2 is created but not sent, version 3 is created and sent. In this case, version 3 replaces version 1 in the "exchange", but version 2 in the application.

Table I.3 – XDSDocumentEntry metadata

Element	Req.	HIS PHMR mapping	Comments
serviceStopTime	(O)	/ClinicalDocument/ documentationOf/serviceEvent/ effectiveTime/high	Contained in PHMR data
size	(R)		
sourcePatientId	(R)	/ClinicalDocument/recordTarget/ patientRole/id	
sourcePatientInfo	(R)	/ClinicalDocument/recordTarget/ patientRole/id	
title	(O)	/ClinicalDocument/title	
typeCode	(R)	/ClinicalDocument/code/@code	
typeCodeDisplayName	(R)	/ClinicalDocument/code/ @displayName	
uniqueId	(R)	/ClinicalDocument/id	
URI	(O)		Not used for HIS as there is no expectation of document retrieval

Table I.4 – XDS submission set metadata for the consent directive document

Apart from those constraints listed in Table I.2 there are no additional constraints for the XDS submission set metadata for the consent directive document.

XDSDocumentEntry metadata requirements for consent directive documents are the same as those mentioned in Table I.3 for PHMR documents, however exceptions are listed in in Table I.5.

Table I.5 – XDSDocumentEntry metadata for the consent directive document

Element	Req.	HIS PHMR mapping	Comments
classCode	(R)	57016-8	
codeSystem	(R)	2.16.840.1.113883.6.1	
codeSystemName	(R)	LOINC	
classCodeDisplayName	(O)	"Privacy Policy Acknowledgment Document"	
formatCode	(R)	"urn:continua:cd:2011"	

Table I-6 – The elements of the confidentiality code system

Name	Value	Comments
Code	"R"	
codeSystem	2.16.840.1.113883.5.25	
codeSystemName	"Confidentiality"	
displayName	"Restricted"	

Table I.7 – The elements of the Continua consent directive code system

Name	Value	Comments
Code	The value **shall** be the same as specified by [HL7 CDA IG].	
codeSystem	2.16.840.1.113883.3.1817.1.2.1	
codeSystemName	"Continua Consent Directive"	
displayName	ID of the consent document	

Table I.8 – The translation of the confidentiality code system to the Continua consent directive code system

Name	Value	Comments
Code	"R"	
codeSystem	2.16.840.1.113883.5.25	
codeSystem Name	"Confidentiality"	
displayName	"Restricted"	
translation	code="<ID of the consent document>" codeSystem=2.16.840.1.113883.3.1817.1.2.1 codeSystemName="Continua Consent Directive" displayName=ID of the consent document	"<> " is a placeholder for the ID of the consent document. Consult Table I.7 for the elements of the Continua Consent Directive code system.

Table I.9 – OID distribution for Personal Connected Health Alliance

OID	Description	Comments
2.16.840.1.113883.3.1817	Organization OID: Continua Health Alliance	
2.16.840.1.113883.3.1817.1	Root OID for the Continua E2E Architecture	
2.16.840.1.113883.3.1817.1.2	Root OID for the E2E Security and Privacy	
2.16.840.1.113883.3.1817.1.3	Root OID for the Personal Health Device -IF	
2.16.840.1.113883.3.1817.1.4	Root OID for the ZigBee Personal Health Device-IF	
2.16.840.1.113883.3.1817.1.5	Root OID for the NFC Personal Health Device-IF	
2.16.840.1.113883.3.1817.1.6	Root OID for the Health and Fitness Service-IF	
2.16.840.1.113883.3.1817.1.7	Root OID for the HIS-IF	
2.16.840.1.113883.3.1817.1.2.1	E2E security and privacy: OID for the Continua Consent Directive code system	
NOTE – The OIDs defined in this table may change for subsequent versions of this Specification.		

I.3 Document source SOAP request/response messages

I.3.1 SOAP request message

The SOAP request message consists of several parts:

1) SOAP header

   a) The header is used for WS-Addressing information as in the following example XDR SOAP request message sent by document source actor [IHE ITI TFS XDR].

   b) This information is useful for the identification of transmission source, target and desired processing.

2) SOAP body

   c) The body contains the ebXML compatible mapping of the document meta-data in the form of a "ProvideAndRegisterDocumentSetRequest" message.

   d) The meta-data is useful in quickly determining the ultimate document dispensation without actually examining the document.

   e) The meta-data is constructed by encoding the XDS meta-data into the underlying ebXML transaction.

3) PHMR document

   f) The PHMR document (and any other required files referenced by the PHMR) would appear in the same message transmission as the SOAP envelope but separated in a message transmission optimization mechanism (MTOM) compatible manner.

I.3.2 SOAP response message

The SOAP response consists of two simple parts:

1) SOAP header

   a) The header is used for WS-Addressing information as in the example below.

   b) This information is useful for matching the response to the corresponding request.

2) SOAP body

   c) The body contains the ebXML compatible response.

Example XDR SOAP request message sent by document source actor[3]

```
<s:Envelope xmlns:s= "http://www.w3.org/2003/05/soap-envelope"
xmlns:a="http://www.w3.org/2005/08/addressing">
  <s:Header>
   <a:Action
     s:mustUnderstand="1">urn:ihe:iti:2007:ProvideAndRegisterDocumentSet-b</a:Action>
   <a:MessageID>urn:uuid:6d296e90-e5dc-43d0-b455-7c1f3eb35d83</a:MessageID>
   <a:ReplyTo>
     <a:Address>http://www.w3.org/2005/08/addressing/anonymous</a:Address>
   </a:ReplyTo>
   <a:To s:mustUnderstand="1">
     http://localhost:2647/XdsService/IHEXDSRepository.svc
   </a:To>
```

[3] Example supplied by IHE. IHE materials used in this document have been extracted from relevant copyrighted materials with permission of Integrating the Healthcare Enterprise (IHE) International. Copies of this standard may be retrieved from the IHE at http://www.ihe.net.

```
  </s:Header>
  <s:Body>
   <ProvideAndRegisterDocumentSetRequest
     xsi:schemaLocation="urn:ihe:iti:xds-b:2007 ../schema/IHE/XDS.b_DocumentRepository.xsd"
     xmlns="urn:ihe:iti:xds-b:2007" xmlns:xsi= "http://www.w3.org/2001/XMLSchema-instance"
     xmlns:lcm="urn:oasis:names:tc:ebxml-regrep:xsd:lcm:3.0" xmlns:rim="urn:oasis:names:tc:ebxml-
regrep:xsd:rim:3.0"
     xmlns:rs="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0">
       <lcm:SubmitObjectsRequest>
         <rim:RegistryObjectList>
          <rim:ExtrinsicObject id="Document01" mimeType="text/xml" objectType="urn:uuid:7edca82f-
054d-47f2-a032-9b2a5b5186c1">
           <rim:Slot name="creationTime">
           <rim:ValueList>
             <rim:Value>20051224</rim:Value>
           </rim:ValueList>
          </rim:Slot>
          <rim:Slot name="languageCode">
           <rim:ValueList>
             <rim:Value>en-us</rim:Value>
           </rim:ValueList>
          </rim:Slot>
          <rim:Slot name="serviceStartTime">
           <rim:ValueList>
             <rim:Value>200412230800</rim:Value>
           </rim:ValueList>
          </rim:Slot>
          <rim:Slot name="serviceStopTime">
           <rim:ValueList>
             <rim:Value>200412230801</rim:Value>
           </rim:ValueList>
          </rim:Slot>
          <rim:Slot name="sourcePatientId">
           <rim:ValueList>
             <rim:Value>ST-1000^^^&amp;amp;1.3.6.1.4.1.21367.2003.3.9&amp;amp;ISO</rim:Value>
           </rim:ValueList>
          </rim:Slot>
          <rim:Slot name="sourcePatientInfo">
           <rim:ValueList>
             <rim:Value>PID-3|ST-1000^^^&amp;amp;1.3.6.1.4.1.21367.2003.3.9&amp;amp;ISO</rim:Value>
            <rim:Value>PID-5|Doe^John^^^</rim:Value>
             <rim:Value>PID-7|19560527</rim:Value>
            <rim:Value>PID-8|M</rim:Value>
            <rim:Value>PID-11|100 Main St^^Metropolis^Il^44130^USA</rim:Value>
           </rim:ValueList>
         </rim:Slot>
         <rim:Name>
           <rim:LocalizedString value="Physical"/>
         </rim:Name>
         <rim:Description/>
         <rim:Classification id="cl01" classificationScheme="urn:uuid:93606bcf-9494-43ec-9b4e-
a7748d1a838d"
           classifiedObject="Document01">
           <rim:Slot name="authorPerson">
            <rim:ValueList>
              <rim:Value>Gerald Smitty</rim:Value>
            </rim:ValueList>
           </rim:Slot>
           <rim:Slot name="authorInstitution">
            <rim:ValueList>
              <rim:Value>Cleveland Clinic</rim:Value>
              <rim:Value>Parma Community</rim:Value>
            </rim:ValueList>
           </rim:Slot>
           <rim:Slot name="authorRole">
            <rim:ValueList>
              <rim:Value>Attending</rim:Value>
            </rim:ValueList>
           </rim:Slot>
           <rim:Slot name="authorSpecialty">
            <rim:ValueList>
              <rim:Value>Orthopedic</rim:Value>
            </rim:ValueList>
           </rim:Slot>
         </rim:Classification>
          <rim:Classification id="cl02" classificationScheme="urn:uuid:41a5887f-8865-4c09-adf7-
e362475b143a"
           classifiedObject="Document01" nodeRepresentation="History and Physical">
           <rim:Slot name="codingScheme">
            <rim:ValueList>
```

```
              <rim:Value>Connect-a-thon classCodes</rim:Value>
             </rim:ValueList>
            </rim:Slot>
            <rim:Name>
             <rim:LocalizedString value="History and Physical"/>
            </rim:Name>
          </rim:Classification>
          <rim:Classification id="cl03" classificationScheme="urn:uuid:f4f85eac-e6cb-4883-b524-
f2705394840f"
            classifiedObject="Document01" nodeRepresentation="1.3.6.1.4.1.21367.2006.7.101">
            <rim:Slot name="codingScheme">
             <rim:ValueList>
               <rim:Value>Connect-a-thon confidentialityCodes</rim:Value>
             </rim:ValueList>
            </rim:Slot>
            <rim:Name>
             <rim:LocalizedString value="Clinical-Staff"/>
            </rim:Name>
          </rim:Classification>
          <rim:Classification id="cl04" classificationScheme="urn:uuid:a09d5840-386c-46f2-b5ad-
9c3699a4309d"
            classifiedObject="Document01" nodeRepresentation="CDAR2/IHE 1.0">
            <rim:Slot name="codingScheme">
             <rim:ValueList>
               <rim:Value>Connect-a-thon formatCodes</rim:Value>
             </rim:ValueList>
            </rim:Slot>
            <rim:Name>
             <rim:LocalizedString value="CDAR2/IHE 1.0"/>
            </rim:Name>
          </rim:Classification>
          <rim:Classification id="cl05" classificationScheme="urn:uuid:f33fb8ac-18af-42cc-ae0e-
ed0b0bdb91e1"
            classifiedObject="Document01" nodeRepresentation="Outpatient">
            <rim:Slot name="codingScheme">
             <rim:ValueList>
               <rim:Value>Connect-a-thon healthcareFacilityTypeCodes</rim:Value>
             </rim:ValueList>
            </rim:Slot>
            <rim:Name>
             <rim:LocalizedString value="Outpatient"/>
            </rim:Name>
          </rim:Classification>
          <rim:Classification id="cl06" classificationScheme="urn:uuid:cccf5598-8b07-4b77-a05e-
ae952c785ead"
            classifiedObject="Document01" nodeRepresentation="General Medicine">
            <rim:Slot name="codingScheme">
             <rim:ValueList>
               <rim:Value>Connect-a-thon practiceSettingCodes</rim:Value>
             </rim:ValueList>
            </rim:Slot>
            <rim:Name>
             <rim:LocalizedString value="General Medicine"/>
            </rim:Name>
          </rim:Classification>
          <rim:Classification id="cl07" classificationScheme="urn:uuid:f0306f51-975f-434e-a61c-
c59651d33983"
            classifiedObject="Document01" nodeRepresentation="34108-1">
            <rim:Slot name="codingScheme">
             <rim:ValueList>
               <rim:Value>LOINC</rim:Value>
             </rim:ValueList>
            </rim:Slot>
            <rim:Name>
             <rim:LocalizedString value="Outpatient Evaluation And Management"/>
            </rim:Name>
          </rim:Classification>
          <rim:ExternalIdentifier id="ei01" registryObject="Document01"
            identificationScheme="urn:uuid:58a6f841-87b3-4a3e-92fd-a8ffeff98427"
            value="SELF-5^^^&amp;1.3.6.1.4.1.21367.2005.3.7&amp;ISO">
            <rim:Name>
             <rim:LocalizedString value="XDSDocumentEntry.patientId"/>
            </rim:Name>
          </rim:ExternalIdentifier>
          <rim:ExternalIdentifier id="ei02" registryObject="Document01"
            identificationScheme="urn:uuid:2e82c1f6-a085-4c72-9da3-8640a32e42ab"
value="1.3.6.1.4.1.21367.2005.3.9999.32">
            <rim:Name>
             <rim:LocalizedString value="XDSDocumentEntry.uniqueId"/>
            </rim:Name>
```

```
         </rim:ExternalIdentifier>
        </rim:ExtrinsicObject>
        <rim:RegistryPackage id="SubmissionSet01">
         <rim:Slot name="submissionTime">
           <rim:ValueList>
            <rim:Value>20041225235050</rim:Value>
           </rim:ValueList>
         </rim:Slot>
         <rim:Name>
           <rim:LocalizedString value="Physical"/>
         </rim:Name>
         <rim:Description>
           <rim:LocalizedString value="Annual physical"/>
         </rim:Description>
         <rim:Classification id="cl08" classificationScheme="urn:uuid:a7058bb9-b4e4-4307-ba5b-
e3f0ab85e12d"
           classifiedObject="SubmissionSet01">
           <rim:Slot name="authorPerson">
            <rim:ValueList>
              <rim:Value>Sherry Dopplemeyer</rim:Value>
            </rim:ValueList>
           </rim:Slot>
           <rim:Slot name="authorInstitution">
            <rim:ValueList>
              <rim:Value>Cleveland Clinic</rim:Value>
              <rim:Value>Berea Community</rim:Value>
            </rim:ValueList>
           </rim:Slot>
           <rim:Slot name="authorRole">
            <rim:ValueList>
              <rim:Value>Primary Surgon</rim:Value>
            </rim:ValueList>
           </rim:Slot>
           <rim:Slot name="authorSpecialty">
            <rim:ValueList>
              <rim:Value>Orthopedic</rim:Value>
            </rim:ValueList>
           </rim:Slot>
         </rim:Classification>
         <rim:Classification id="cl09"
           classificationScheme="urn:uuid:aa543740-bdda-424e-8c96-df4873be8500"
           classifiedObject="SubmissionSet01" nodeRepresentation="History and Physical">
           <rim:Slot name="codingScheme">
            <rim:ValueList>
              <rim:Value>Connect-a-thon contentTypeCodes</rim:Value>
            </rim:ValueList>
           </rim:Slot>
           <rim:Name>
            <rim:LocalizedString value="History and Physical"/>
           </rim:Name>
         </rim:Classification>
         <rim:ExternalIdentifier id="ei03" registryObject="SubmissionSet01"
           identificationScheme="urn:uuid:96fdda7c-d067-4183-912e-bf5ee74998a8"
           value="1.3.6.1.4.1.21367.2005.3.9999.33">
           <rim:Name>
            <rim:LocalizedString value="XDSSubmissionSet.uniqueId"/>
           </rim:Name>
         </rim:ExternalIdentifier>
         <rim:ExternalIdentifier id="ei04" registryObject="SubmissionSet01"
           identificationScheme="urn:uuid:554ac39e-e3fe-47fe-b233-965d2a147832"
           value="3670984664">
           <rim:Name>
            <rim:LocalizedString value="XDSSubmissionSet.sourceId"/>
           </rim:Name>
         </rim:ExternalIdentifier>
         <rim:ExternalIdentifier id="ei05" registryObject="SubmissionSet01"
           identificationScheme=
            "urn:uuid:6b5aea1a-874d-4603-a4bc-96a0a7b38446"
            value="SELF-5^^^&amp;amp;1.3.6.1.4.1.21367.2005.3.7&amp;amp;ISO">
           <rim:Name>
            <rim:LocalizedString value="XDSSubmissionSet.patientId"/>
           </rim:Name>
         </rim:ExternalIdentifier>
        </rim:RegistryPackage>
        <rim:Classification id="cl10" classifiedObject="SubmissionSet01"
         classificationNode="urn:uuid:a54d6aa5-d40d-43f9-88c5-b4633d873bdd"/>
        <rim:Association id="as01" associationType="HasMember"
         sourceObject="SubmissionSet01" targetObject="Document01">
         <rim:Slot name="SubmissionSetStatus">
           <rim:ValueList>
```

```
            <rim:Value>Original</rim:Value>
           </rim:ValueList>
         </rim:Slot>
        </rim:Association>
       </rim:RegistryObjectList>
      </lcm:SubmitObjectsRequest>
      <Document id="Document01">UjBsR09EbGhjZ0dTQUxNQUFBUUNBRU1tQ1p0dU1GUXhEUzhi</Document>
    </ProvideAndRegisterDocumentSetRequest>
  </s:Body>
</s:Envelope>
```

Example XDR SOAP response message sent by document recipient actor[4]

```
<s:Envelope xmlns:s="http://www.w3.org/2003/05/soap-envelope"
xmlns:a="http://www.w3.org/2005/08/addressing">
  <s:Header>
   <a:Action s:mustUnderstand="1">
     urn:ihe:iti:2007:ProvideAndRegisterDocumentSet-bResponse
   </a:Action>
   <a:RelatesTo>urn:uuid:6d296e90-e5dc-43d0-b455-7c1f3eb35d83</a:RelatesTo>
  </s:Header>
  <s:Body>
   <rs:RegistryResponse xsi:schemaLocation="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0
../schema/ebRS/rs.xsd"
     status="urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Success"
xmlns:rs="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0"
     xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"/>
  </s:Body>
</s:Envelope>
```

[4] Example supplied by IHE

Appendix II

Security recommendations

(This appendix does not form an integral part of this Recommendation.)

XDR and XDM have security considerations that require participant attention. The primary considerations are ensuring that the node to which the HIS sender is transmitting is the correct/authorized node and that the document is not intercepted/examined/altered while in transmission.

As XDR and XDM are the simplified members of the XDS family of profiles, they have some simplifying assumptions that make this more straightforward.

CONF-PHMR-1: The base consideration is that this movement of personal health information is not ad hoc. That is, the document source and document recipient have a prior knowledge of each other and have each reached a comfort level that the other is a satisfactory partner in this transaction with all its social, business and legal ramifications.

CONF-PHMR-2: An additional consideration is that this transaction is a point-to-point private transaction between the two parties with no other parties involved.

The first assumption allows for the participants to work out specifics of the transfer (such as transport method, IP address, key certificates, e-mail addresses, etc.) as part of their formal arrangements. The second assumption allows for common cryptographic techniques to supply the rest of the puzzle.

XDR requires the usage of transport level security (TLS) as the minimum transmission security. In server environments, this is quite often the underlying technology already operational at the participant's site HTTPS implementation. Thus, by utilizing HTTPS for the SOAP message exchange, the security requirements are met. A cipher suite of TLS_RSA_WITH_AES_128_CBC_SHA is recommended.

For XDM, transmission security depends on the exact delivery method chosen. For e-mail transfers, S-MIME is required.

Appendix III

ISO/IEEE 11073-10101 to SNOMED CT and UCUM

(This appendix does not form an integral part of this Recommendation.)

III.1 Observation types mapping to SNOMED CT

NOTE – Even though the final ISO/IEEE 11073 Reference IDs and numeric code assignments have not all been finalized at the present time, the following table provides adequate guidance to map IEEE device terminology into SNOMED CT.

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Plasma glucose level (-10417)	MDC_CONC_GLU_CAPILLARY_PLASMA 2::29116	434911002	2774413018	Plasma glucose concentration	2774414012	122554006 | Capillary blood specimen (specimen)	

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT					Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Plasma glucose level (-10417)	MDC_CONC_GLU_VENOUS_PLASMA 2::29124	434911002	2774413018	Plasma glucose concentration	2774414012	122555007 | Venous blood specimen (specimen) 119298005 | Mixed venous blood specimen (specimen)	

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Plasma glucose level (-10417)	MDC_CONC_GLU_ARTERIAL_PLASMA 2::29132	434911002	2774413018	Plasma glucose concentration	2774414012	122552005 | Arterial blood specimen (specimen)	

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Plasma glucose level (-10417)	CONC_GLU_UNDETERMINED_PLASMA 2::29296	434911002	2774413018	Plasma glucose concentration	2774414012	N/A	

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Blood glucose level (-10417)	MDC_CONC_GLU_CAPILLARY_WHOLEBLOOD 2::29112	434912009	2774415013	Blood glucose concentration	2774416014	122554006 | Capillary blood specimen (specimen) 119298005 | Mixed venous blood specimen (specimen)	

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT					Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Blood glucose level (-10417)	MDC_CONC_GLU_VENOUS_WHOLEBLOOD 2::29120	434912009	2774415013	Blood glucose concentration	2774416014	122555007 | Venous blood specimen (specimen) 119298005 | Mixed venous blood specimen (specimen)	

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT					Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Blood glucose level (-10417)	MDC_CONC_GLU_ARTERIAL_WHOLEBLOOD 2::29128	434912009	2774415013	Blood glucose concentration	2774416014	122552005 | Arterial blood specimen (specimen) 119298005 | Mixed venous blood specimen (specimen)	
Plasma glucose level (-10417)	MDC_CONC_GLU_UNDETERMINED_WHOLEBLOOD 2::29292	434912009	2774415013	Blood glucose concentration	2774416014	N/A	

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Glucose control measurement (-10417)	MDC_CONC_GLU_CONTROL 2::29136	434913004	2774417017	Glucose concentration in quality control reagent	2774418010		
Interstitial fluid glucose level (-10417)	MDC_CONC_GLU_ISF 2::29140	434910001	2774412011	Interstitial fluid glucose concentration	2774411016		
Haemoglobin A1C finding (-10417)	MDC_CONC_HBA1C 2::29148	365845005	489331011	Haemoglobin A1C – diabetic control finding	772274010		

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Coagulation ratio – INR (-10418)	MDC_RATIO_INR_COAG 2::29188	165581004	257472014	International normalised ratio	165581004		
Prothrombin time (-10418)	MDC_TIME_PD_COAG 2::29192	396451008	1776384018	Prothrombin time			
Coagulation quick value (-10418)	MDC_QUICK_VALUE_COAG 2::29196						

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
International Sensitivity Index – ISI (-10418)	MDC_ISI_COAG 2::29200						
INR Control Measurement (-10418)	MDC_COAG_CONTROL 2::29204						
Body mass (weight) (-20601)	MDC_MASS_BODY_ACTUAL 2::57664	27113001	45352010	Body weight	757644016		

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Body height (-10415)	MDC_LEN_BODY_ACTUAL 2::57668	50373000	495662010	Body height measure	788154012		
Body mass index (-10415)	MDC_RATIO_MASS_BODY_LEN_SQ 2::57680	60621009	100716012	Body mass index	799594012		
Systolic pressure (-10407)	MDC_PRESS_BLD_NONINV_SYS 2::18949	271649006	106507015	Systolic blood pressure	664067013		
Diastolic pressure (-10407)	MDC_PRESS_BLD_NONINV_DIA 2::18950	271650006	406508013	Diastolic blood pressure	664068015		

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Mean arterial pressure (-10407)	MDC_PRESS_BLD_NONINV_MEAN 2::18951	6797001	500884018	Mean blood pressure	807753012	NOTE – Must be rendered as mean blood press not mean arterial pressure	
Pulse (-10407)	MDC_PULS_RATE_NON_INV 2::18474	78564009	130365016	Pulse rate	819518016		
Body water (-10420)	MDC_BODY_WATER	251837008	375163013	Total body water (observable entity)			

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Body fat (-10420)	MDC_BODY_FAT	248361005	370758016	Total body fat (observable entity)			
Body fat free (-10420)	MDC_BODY_FAT_FREE	248363008	370760019	Fat-free mass (observable entity)			
Heart rate (-10406)	MDC_ECG_HEART_RATE	364075005	487210016	Heart rate (observable entity)			

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Body temperature (-10408)	MDC_TEMP_BODY 2::19292	386725007	1480858013	Body temperature	1460904011		
Body temperature (Finger) (-10408)	MDC_TEMP_FINGER 2::57360	433588001	*2771281010*	Temperature of digit of hand	*2760794019*		
Body temperature (Ear) (-10408)	MDC_TEMP_EAR 2::57356	415974002	2534421019	Tympanic temperature	2530951014		

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Body temperature (Toe) (-10408)	MDC_TEMP_TOE 2::57376	433776001	*2768039016*	Temperature of toe	*2745011013*		
Body temperature (Gastro) (-10408)	MDC_TEMP_GIT 2::57384	431598003	*2769062014 (US)*	Temperature of esophagus	*2747764015*	*2769063016 (UK) Temperature of oesophagus*	

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Body temperature (Armpit) (-10408)	MDC_TEMP_AXILLA 2::57380	415882003	2534419012	Auxiliary temperature	2530949010		
Body temperature (Oral) (-10408)	MDC_TEMP_ORAL 2::57352	415945006	2534418016	Oral temperature	253094019		

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Body temperature (Rectal) (-10408)	MDC_TEMP_RECT 2::57348	307047009	450211011	Rectal temperature	703520017		
Body temperature (Tympanic) (-10408)	MDC_TEMP_TYMP 2::19320	415974002	2534421019	Tympanic temperature	2530951014		

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT					Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
SpO2 (-10404)	MDC_PULS_OXIM_SAT_O2 2::19384	431314004	*2772010012*	Peripheral oxygen saturation	*2735642016*	*2767654013* | SpO2 – saturation of peripheral oxygen	
Pulse rate (-10404)	MDC_PULS_OXIM_PULS_RATE 2::18458	78564009	130365016	Pulse rate	819518016		

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT					Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Pulse amplitude (-10404)	MDC_PULS_OXIM_PERF_REL 2::19376 Or MDC_SAT_O2_QUAL 2::19248	431591009	*2769937011*	Pulse waveform amplitude using pulse oximetry	*2736894010*		
Plethysmographic waveform (-10404)	MDC_PULS_OXIM_PLETH 2::19380	250864000	373962018	Plethysmograph waveform	*641309010*		

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Peak expiratory flow (-10421)	MDC_FLOW_AWAY_EXP_FORCED_PEAK 2::21512	251940009	375280019	Serial peak expiratory flow rate	*642506016*		
Personal best of PEF (-10421)	MDC_FLOW_AWAY_EXP_FORCED_PEAK_PB 2::21513	251936000	375276012	Best ever peak expiratory flow rate	*642501014*		
Forced expiratory volume over 1 second (-10421)	MDC_VOL_AWAY_EXP_FORCED_1S 2::21514	59328004	498401010	Forced expired volume in 1 second	*798158012*		

Table III.1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Forced expiratory volume over 6 seconds (-10421)	MDC_VOL_AWAY_EXP_FORCED_EXP_6S 2::21515	165041004	256687019	Forced expired volume	*546438012*	The duration shall express 6s interval	New SNOMED concept is needed for MDC code.

III.2 Events and attributes types mapping to SNOMED CT

NOTE – Even though the final ISO/IEEE 11073 Reference IDs and numeric code assignments have not been all finalized at the present time, the following table provides adequate guidance to map IEEE device terminology into SNOMED CT.

Table III.2 – Events and attributes types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT					Notes
		Concept ID	Description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Sample location (-10417)	MDC_CTXT_GLU_SAMPLE LOCATION 128:29236						
Sample location attribute (-10417)	Finger MDC_CTXT_GLU_SAMPLE LOCATION_FINGER 128::29240	125685002	473565013	Digit of hand structure	729542015		
Sample location attribute (-10417)	Alternative Site Testing (AST) MDC_CTXT_GLU_SAMPLE LOCATION_AST 128::29244						
Sample location attribute (-10417)	Earlobe MDC_CTXT_GLU_SAMPLE LOCATION_EARLOBE 128::29248	113327001	383219015	Pinna structure	648683014		
Control solution indicator attribute (-10417)	Control Solution MDC_CTXT_GLU_SAMPLE LOCATION_CTRLSOLUTIO N 128::29252						Mapped via observation of type: MDC_CONC_GLU_CONT ROL

Table III.2 – Events and attributes types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT					Notes
		Concept ID	Description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Measurement condition (-10417)	MDC_CTXT_GLU_MEAL 128:29256						
Measurement condition attribute (-10417)	MDC_CTXT_GLU_MEAL_PREPRANDIAL Pre-Prandial (or Pre-Meal) 128::29260	307165006	450357011	Before meal	703654021		
Measurement condition attribute (-10417)	MDC_CTXT_GLU_MEAL_POSTPRANDIAL Post-Prandial (or Post-Meal) 128::29264	225758001	339227016	After food	613042015		
Measurement condition attribute (-10417)	MDC_CTXT_GLU_MEAL_FASTING 128::29268	16985007	478017015	Fasting	744117012		
Measurement condition attribute (-10417)	MDC_CTXT_GLU_MEAL_BEDTIME 128::29300	307155000	450339010	Before sleeping	703641017		Bedtime
Measurement condition attribute (-10417)	MDC_CTXT_GLU_MEAL_CASUAL 128::29272	255226008	380387010	Random	646234012		
Tester (-10417)	MDC_CTXT_GLU_TESTER 128:29276						
Tester attribute (-10417)	MDC_CTXT_GLU_TESTER_SELF 128::29280						Mapped via HL7 CDA information model

Table III.2 – Events and attributes types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT					Notes
		Concept ID	Description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Tester attribute (-10417)	MDC_CTXT_GLU_TESTER_HCP 128::29284						Mapped via HL7 CDA information model
Tester attribute (-10417)	MDC_CTXT_GLU_TESTER_LAB 128::29288						Mapped via HL7 CDA information model
SpO2 – fast-response (-10404)	MDC_MODALITY_FAST 2::19508	433204000	*2768695014*	Rate of sampling of peripheral oxygen saturation by device	*2743645015*	NOTE – This must be used in conjunction with 277748003 Fast (qualifier value)	The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time.
SpO2 – slow-response (-10404)	MDC_MODALITY_SLOW 2::19512	433204000	*2768695014*	Rate of sampling of peripheral oxygen saturation by device	*2743645015*	NOTE – This must be used in conjunction with 255361000 Slow (qualifier value)	The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time.
SpO2 – spot-check (-10404)	MDC_MODALITY_SPOT 2::19516	431314004	*2772010012*	Peripheral oxygen saturation	*2735642016*	*2767654013* | SpO2 – saturation of peripheral oxygen	The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time.
SpO2 – precise pulse (-10404)	MDC_TRIG_BEAT_MAX_INRUSH 2::53259						The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time.

III.3 Events and attributes not mapped to SNOMED CT

NOTE – Even though the final ISO/IEEE 11073 Reference IDs and numeric code assignments have not all been finalized at the present time, the following table provides an indication of IEEE device terminology that was not mapped into SNOMED CT.

Table III.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
Pulse events (-10404)	MDC_TRIG 2::53250				
Pulse events (-10404)	MDC_TRIG_BEAT 2::53251 Value for attribute MDC_TRIG				
Compound blood pressure measurement (-10407)	MDC_PRESS_BLD_NONINV 2::18948				
SpO2 threshold conditions (-20601)	MDC_ATTR_MSMT_STAT 1::2375				
Alarm condition (-10404)	MDC_ATTR_AL_COND 1::2476				
SpO2 threshold conditions (-10404)	MDC_ATTR_AL_OP_STAT 1::2310				
SpO2 threshold conditions (-10404)	MDC_ATTR_LIMIT_CURR 1::2356				
SpO2 threshold conditions (-10404)	MDC_ATTR_AL_OP_TEXT_STRING 1::2478				
Pulse event placeholder (-10404)	MDC_METRIC_NOS 2::61439				

Table III.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
Pulse characteristics event (-10404)	Event: MDC_PULS_OXIM_PULS_CHAR 2::19512				
Pulse characteristics event (-10404)	Value for attribute MDC_PULS_OXIM_PULS_CHAR Attributes (not coded) Perfusion or quality of the detected pulse is marginal – pulse-qual-marginal Perfusion or quality of the detected pulse is minimal – pulse-qual-minimal Perfusion or quality of the detected pulse is unacceptable – pulse-qual-unacceptable				Bit values will need local coding
Pulse device and sensor conditions (-10404)	Event: MDC_PULS_OXIM_DEV_STATUS 2::19532				

Table III.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
Pulse device and sensor conditions (-10404)	Value for attribute MDC_PULS_OXIM_DEV_STATUS Attributes: Agent reports that the sensor is disconnected from the instrument. – sensor-disconnected Agent reports that the sensor is malfunctioning or faulty. – sensor-malfunction Agent reports that the sensor is not properly attached or has been dislodged, preventing accurate measurement. – sensor-displaced An unsupported sensor is connected to the Agent – sensor-unsupported Agent reports that sensor is not connected to the user – sensor-off Signal analysis is currently in progress prior to measurement availability – sensor-searching Agent reports that there is interference due to ambient light or electrical phenomena – sensor-interference Agent determines that a questionable pulse is detected – signal-pulse-questionable Agent detects a non-pulsatile signal – signal-non-pulsatile Agent reports that the signal is erratic or is not plausible – signal-erratic Agent reports a consistently low perfusion condition exists – signal-low-perfusion Agent reports a poor signal exists, possibly affecting accuracy – signal-poor Agent reports that the incoming signal cannot be analyzed or is inadequate for producing a meaningful result. – signal-inadequate Agent has determined that some irregularity has been detected while processing the signal. – signal-processing-irregularity A general device fault has occurred in the Agent – device-equipment-malfunction An Extended Display Update is currently active – device-extended-update				Bit values will need local coding

Table III.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
Medication (insulin) event (-10417)	Event: MDC_CTXT_MEDICATION 128::29188				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_RAPIDACTING 128::29192 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_SHORTACTING 128::29196 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_INTERMEDIATEACTING 128::29200 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_LONGACTING 128::29204 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_PREMIX 128::29208 Value for attribute MDC_CTXT_MEDICATION				

Table III.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
Subjective health event (-10417)	Event: MDC_CTXT_GLU_HEALTH 128::29212				
Subjective health event (-10417)	MDC_CTXT_GLU_HEALTH_MINOR 128::29216 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective health event (-10417)	MDC_CTXT_GLU_HEALTH_MAJOR 128::29220 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective health event (-10417)	MDC_CTXT_GLU_HEALTH_MENSES 128::29224 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective health event (-10417)	MDC_CTXT_GLU_HEALTH_STRESS 128::29228 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective health event (-10417)	MDC_CTXT_GLU_HEALTH_NONE 128::29232 Value for attribute MDC_CTXT_GLU_HEALTH				
Exercise activity (-10417)	MDC_CTXT_GLU_EXERCISE 128::29152				

Table III.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
Dietary intake event (-10417)	Event: MDC_CTXT_GLU_CARB 128::29156				
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_BREAKFAST 128::29160 Value for attribute MDC_CTXT_GLU_CARB				
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_LUNCH 128::29164 Value for attribute MDC_CTXT_GLU_CARB				
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_DINNER 128::29168 Value for attribute MDC_CTXT_GLU_CARB				
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_SNACK 128::29172 Value for attribute MDC_CTXT_GLU_CARB				
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_DRINK 128::29176 Value for attribute MDC_CTXT_GLU_CARB				
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_SUPPER 128::29180 Value for attribute MDC_CTXT_GLU_CARB				

Table III.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_BRUNCH 128::29184 Value for attribute MDC_CTXT_GLU_CARB				
Meter status (-10417)	MDC_GLU_METER_DEV_STATUS 128::29144				
Fixed medication dispensed event (-10472)	MDC_AI_MED_DISPENSED_FIXED 130::13312				Mapped via the HL7 CDA medication section
Variable medication dispensed Event (-10472)	MDC_AI_MED_DISPENSED_VARIABLE 130::13313				Mapped via the HL7 CDA medication section [ANSI/HL7 CDA]
User feedback event (-10472)	MDC_AI_MED_FEEDBACK 130::13315				Mapped via the HL7 Framework for Questionnaire Assessments (Universal Realm) [HL7 CDA R2 QA]
Status reporter event (-10472)	Value for attribute MDC_AI_MED_STATUS 130::13314				
Body fat (-10420)	MDC_BODY_FAT 2::57676				
Body water (-10420)	MDC_BODY_WATER 2::57692				

Table III.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
Fat free mass (-10420)	MDC_MASS_BODY_FAT_FREE 2::57684				
Soft lean mass (-10420)	MDC_MASS_BODY_SOFT_LEAN 2::57688				
Heart rate (-10406)	MDC_ECG_HEART_RATE 2::16770				
Instantaneous heart rate (-10406)	MDC_ECG_HEART_RATE_INSTANT 128::21982				
R-R interval (-10406)	MDC_ECG_TIME_PD_RR_GL 2::16168				
ECG lead unspecified (-10406)	MDC_ECG_ELEC_POTL 2::256				
ECG lead augmented voltage foot (aVF) (-10406)	MDC_ECG_ELEC_POTL_AVF 2::320				
ECG lead augmented voltage left (aVL) (-10406)	MDC_ECG_ELEC_POTL_AVL 2::319				
ECG lead augmented voltage right (aVR) (-10406)	MDC_ECG_ELEC_POTL_AVR 2::318				
ECG lead I (-10406)	MDC_ECG_ELEC_POTL_I 2::257				
ECG lead II (-10406)	MDC_ECG_ELEC_POTL_II 2::258				

Table III.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
ECG lead III (-10406)	MDC_ECG_ELEC_POTL_III 2::317				
ECG lead V1 (-10406)	MDC_ECG_ELEC_POTL_V1 2::259				
ECG lead V2 (-10406)	MDC_ECG_ELEC_POTL_V2 2::260				
ECG lead V3 (-10406)	MDC_ECG_ELEC_POTL_V3 2::261				
ECG lead V4 (-10406)	MDC_ECG_ELEC_POTL_V4 2::262				
ECG lead V5 (-10406)	MDC_ECG_ELEC_POTL_V5 2::263				
ECG lead V6 (-10406)	MDC_ECG_ELEC_POTL_V6 2::264				
ECG device status (-10406)	Event: MDC_ECG_DEV_STAT 128::21976				

Table III.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
ECG device status (-10406)	Value for attribute MDC_ECG_DEV_STAT Attributes: Agent reports loss of lead wire or electrode connection (lead unspecified). – leadwire-loss Agent reports loss of lead signal (lead unspecified). – leadsignal-loss Agent reports loss of lead wire or electrode connection (first lead). – leadwire-loss-first-lead Agent reports loss of lead signal (first lead). – leadsignal-loss-first-lead Agent reports loss of lead wire or electrode connection (second lead). – leadwire-loss-second-lead Agent reports loss of lead signal (second lead). – leadsignal-loss-second-lead Agent reports loss of lead wire or electrode connection (third lead). – leadwire-loss-third-lead Agent reports loss of lead signal (third lead). – leadsignal-loss-third-lead				
ECG context data trigger event (-10406)	Event: MDC_ECG_EVT_CTXT_GEN 128:: 21977				

Table III.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
ECG context data trigger event (-10406)	Value for attribute MDC_ECG_EVT_CTXT_GEN MDC_ECG_EVT_CTXT_USER 128::21978				
ECG context data trigger event (-10406)	Value for attribute MDC_ECG_EVT_CTXT_GEN MDC_ECG_EVT_CTXT_PERIODIC 128::21979				
ECG context data trigger event (-10406)	Value for attribute MDC_ECG_EVT_CTXT_GEN MDC_ECG_EVT_CTXT_DETECTED 128::21980				
ECG context data trigger event (-10406)	Value for attribute MDC_ECG_EVT_CTXT_GEN MDC_ECG_EVT_CTXT_EXTERNAL 128::21981				

III.4 ISO/IEEE 11073-10101 Unit elements mapping to UCUM

Table III.4 – ISO/IEEE 11073-10101 Unit elements (MDC_PART_DIM) mapping to UCUM

11073 Reference ID	Symbol (informative)	UCUM unit code (case sensitive)
MDC_DIM_PERCENT	%	%
MDC_DIM_BEAT_PER_MIN	Bpm	{beat }/min
MDC_DIM_MMHG	mmHg	mm[Hg]
MDC_DIM_KILO_PASCAL	kPa	kPa
MDC_DIM_DEGC	˚C	Cel
MDC_DIM_FAHR	˚F	[degF]
MDC_DIM_KILO_G	kg	kg
MDC_DIM_LB	lb	[lb_av]
MDC_DIM_CENTI_M	cm	cm
MDC_DIM_INCH	in	[in_i]
MDC_DIM_KG_PER_M_SQ	kg/m^2	kg/m2
MDC_DIM_MILLI_MOLE_PER_L	mmol/L	mmol/L
MDC_DIM_KCAL	Cal	[Cal]
MDC_DIM_MILLI_G_PER_DL	mg/dL	mg/dL
MDC_DIM_DIMLESS		1
MDC_DIM_MILLI_L	mL	mL
MDC_DIM_MILLI_G	mg	mg
MDC_DIM_INTL_UNIT	IU	[iU]
MDC_DIM_L_PER_MIN	L/min	L/min
MDC_DIM_L	L	L
MDC_DIM_MICRO_SEC	us	us
MDC_DIM_MILLI_SEC	ms	ms
MDC_DIM_MILLI_VOLT	mV	mV
MDC_DIM_PER_SEC	s-1	/s
MDC_DIM_TICK	tick	

Appendix IV

Mapping from the Continua Services to the HL7 personal health monitoring report object model

(This appendix does not form an integral part of this Recommendation.)

IV.1 Introduction

The Continua HIS interface utilizes the personal healthcare monitoring report (PHMR) [HL7 CDA-PHMR] document to convey information to HR systems. As the PHMR is meant to be a report detailing a wide assortment of patient-centred information, the information conveyed could be from a myriad of data sources. These data sources may be in-home devices but they can also be information gathered at other points in the complete health care spectrum.

This document is based on the HL7 V3 architecture and is a derivative of the clinical document architecture release 2 (CDA R2). As such, it is a structured XML based file that has specified clauses for various types of health information.

Placing the data derived from Health & Fitness service interface messages (PCD-01) entails placing the data in specific document clauses in their proper format. Along with any desired data from other sources, this total set of information would comprise a single PHMR document.

The discussion that follows centres on the Health & Fitness service interface and only gives guidance on how to place Health & Fitness service interface derived data in the report.

IV.2 Base mapping strategy

At a high level, information is split up and reported in various clauses of the PHRM depending on the type of data and the type of device.

IV.3 Device information

Information on the device itself is placed in the *Medical Equipment* clause of the PHMR. This device information should be formatted into a *Device Definition Organizer* element. At a minimum, the data should include the system type, system model, system manufacturer, system ID, production specification and whether the device is regulated.

IV.4 Observation information

The PHRM specifies that the blood pressure, temperature, O2 saturation, respiratory rate and pulse observation data be conveyed in the *Vital Signs* clause. All other information is conveyed in the *Results* clause.

For Continua HIS usage, the CDG place some additional constraints on the data reported. The guidelines contain a table of mappings from IEE MDC codes to SNOMED codes.

If the value being reported is contained in the guideline mapping table, then the measurement must be reported using the SNOMED code and there should be a translation code element that specifies the corresponding (probably original) IEEE MDC code.

If the value being reported is not contained in the guideline mapping table, then the observation is simply reported using the IEEE MDC code.

IV.5 Device information

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               <th>Regulated</th>
          </tr>
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               <td>Pulse Master 2000</td>
               <td>Acme</td>
               <td>1F-3E-46-78-9A-BC-DE-F1</td>
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                         Part Number: 69854<br/>
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                         Software Revision: 1.1<br/>
                         Protocol Revision: 1.0<br/>
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               <td>Regulated</td>
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displayName="Arterial pressure monitor"/>
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example (no shalls for the labels used below)-->
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                    Part number: 69854
                    Hardware revision: 2.1
                    Software revision: 1.1
                    Protocol revision: 1.0
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IV.6 Observation information

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    <table border="1" width="100%">
      <tBody>
        <tr>
            <th>Date/Time</th>
            <th>Body Temp</th>
            <th>Finger Temp</th>
            <th>Oral Temp</th>
        </tr>
        <tr>
            <td>20080501104033</td>
            <td>99.9 deg F</td>
            <td>88.8 deg F</td>
            <td>37.5 deg C</td>
        </tr>
      </tBody>
    </table>
 </text>
 <entry typeCode="DRIV">
    <organizer classCode="CLUSTER" moodCode="EVN">
      <!-- Vital sign data/ Test Groups -->
      <!-- A VITAL SIGNS ORGANIZER IS USED TO GROUP RELATED -->
      <templateId root="2.16.840.1.113883.10.20.1.35"/>
      <id root="b606a959-baab-4836-84a8-97c4e9857533"/>
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displayName="Vital signs"/>
      <statusCode code="completed"/>
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          <observation classCode="OBS" moodCode="EVN">
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               <id root="975c2f3b-2bd4-4e45-aed1-84af9ff51b10"/>
               <code code="386725007" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Body Temperature">
                    <translation code="MDC_TEMP_BODY"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Body
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               </code>
               <statusCode code="completed"/>
               <effectiveTime value="20080501104033-0600"/>
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                    <participantRole>
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                    </participantRole>
               </participant>
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       </component>
       <component>
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               <templateId root="2.16.840.1.113883.10.20.9.8"/>
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codeSystemName="SNOMED CT" displayName="Temperature of digit of hand">
                    <translation code="MDC_TEMP_FINGER"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Finger
Temperature"/>
               </code>
               <statusCode code="completed"/>
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assigningAuthorityName="EUI-64" extension="1A-34-46-78-9A-BC-DE-F3"/>
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          </observation>
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                    </participantRole>
               </participant>
          </observation>
       </component>
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    </organizer>
 </entry>
</section>
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Appendix V

Delivery of PHMR data within national and regional contexts

(This appendix does not form an integral part of this Recommendation.)

V.1 Delivery of PHMR data via ONC DIRECT

The DIRECT project of the United States Department of Health and Human Services – Health Information Technology – defines a mechanism to securely exchange health data between trusted parties using electronic mail. The purpose of ONC's (Office of the National Coordinator for Health Information Technology of the United States) DIRECT project is outlined in [b-DIRECT].

Within Continua the use of ONC's DIRECT aligns the Continua guidelines with those of the ONC's Meaningful Use directives. Thus a product that wishes to deliver Continua data from PHDs while meeting the United States' ONC's Meaningful Use requirements can follow the guidelines for a HIS Sender – ONC_DIRECT.

This clause documents a certified capability class that builds on top of the existing HIS sender capability class (HIS Sender – Indirect Communication). The capability class is named HIS Sender – ONC_DIRECT. It defines how the ZIP package created using the HIS Sender – Indirect communication capability class is to be sent when using email. The HIS Sender ONC_DIRECT certified capability class specifies three items:

1. Generate the ZIP package to be exchanged in accordance with HIS Sender – Indirect Communications.
2. Send the ZIP package using the simple mail transport protocol (SMTP) [b-IETF RFC 5321].
3. When sending the ZIP package using SMTP follow the specifications of ONC's DIRECT.

See [b-ONC-DIRECT-AS] for additional details.

The relevant certified capability classes and messaging guidelines are given in the Table V.1 and Table V.2.

Table V.1 – HIS certified capability classes and guidelines for ONC_DIRECT

	Network messaging	Relevant guidelines
HIS Sender – ONC_DIRECT	Yes	6.2.2.2, 6.2.3.2, 6.2.3.3, 6.2.4, 6.2.5.2
HIS Receiver – ONC_DIRECT	Not Certified	6.2.2.2, 6.2.3.2, 6.2.3.3, 6.2.4, 6.2.5.2

Table V.2 – Messaging guidelines applicable to ONC_DIRECT

Name	Description	Comments
HIS-ONC-DIRECT-CONFORM-APPLICABILITY	A HIS sender – ONC-DIRECT and an HIS receiver -ONC-DIRECT **shall** conform to the requirements specified in the Applicability Statement for Secure Health Transport [b-ONC-DIRECT-AS]	
HIS-ONC-DIRECT-CONFORM-XDM	A HIS sender – ONC-DIRECT and an HIS receiver -ONC-DIRECT **shall** conform to the XDR and XDM for Direct Messaging Specification [b-ONC-DIRECT-X]	
HIS-SENDER-ONC-DIRECT	A HIS sender – ONC-DIRECT **shall** support the interaction pattern of a RFC 5322 + XDM sender as defined in the table on page 6 of [b-ONC-DIRECT-X].	

Bibliography

For a list of non-normative references and publications that contain further background information, see [ITU-T H.810].

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