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SERIES H: AUDIOVISUAL AND MULTIMEDIA SYSTEMS

E-health multimedia services and applications – Personal
health systems

Interoperability design guidelines for personal health systems: WAN interface: Questionnaires

Recommendation ITU-T H.812.2



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Recommendation ITU-T H.812.2

Interoperability design guidelines for personal health systems: WAN interface: Questionnaires

Summary

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

Patient reported outcomes measures (PROMs) are increasingly needed to improve the cost effectiveness and quality of health services. Recommendation ITU-T H.812.2 defines design guidelines for the Questionnaire certified device class (CDC), whose function is to enable the interoperable exchange of PROMs (also known as questionnaires) across the WAN-IF of the Continua end-to-end architecture.

The questionnaires are represented according to the HL7 Implementation Guide (IG) for CDA R2 Questionnaire Form Definition (QFD) document (HL7 CDA QFD). The QFD document captures the health survey questions or question sets to be administered to a patient. The QFD document enables the definition of questions for surveying the patient's perception on their health and the impact that any treatments or adjustments to lifestyle have had on their quality of life. QFD documents may carry a variety of clinical and non-clinical questions and branching logic in order to present the patient with a dynamic health survey for assessing health status including, but not limited to, the patient's functional, cognitive and physiological characteristics. Authors of the QFD documents may include information about disease management organizations, primary care physicians, health and fitness coaches, chronic condition monitors, post-acute and long-term care organizations.

The response to a questionnaire is then represented according to the HL7 Implementation Guide (IG) for CDA R2 Questionnaire Response (QR) document (HL7 CDA QRD). Authors of the QR documents may include the patients who are under the care of disease management organizations, primary care physicians, health and fitness coaches, chronic condition monitors, and post-acute and long-term care providers or their agents.

For the exchange of QFD and QR documents, this Recommendation specifies and profiles the use of the HL7 hData record format and OMG hData REST Binding for RLUS. For security, this Recommendation further profiles the use of OAuth 2.0 and TLS v1.1.

Recommendation ITU-T H.812.11 is part of the "ITU-T H.810 interoperability design guidelines for personal health systems" subseries, which is outlined in the table below:

Mapping of CDG 2013, ITU-T H.810 and restructured ITU-T H.810-series

Part	Elements	Clauses in the 2013 CDG "Endorphin"	Clauses in ITU-T H.810 (2013)	Restructured ITU-T H.810-series (2015)
Part 0	System overview	Up to clause 3, plus Annex A and Appendix G	Up to clause 6, plus Annex A and Appendix V	ITU-T H.810 – System overview
Part 1	TAN/ PAN/ LAN	Clauses 4 to 7, Appendices C, D, M	Clauses 7 to 10, Appendices I, II, XI	ITU-T H.811 – TAN-PAN-LAN interface
Part 2	WAN	Clause 8, Appendices H, I, J, K	Clause 11; Appendices VI, VII, VIII, IX	ITU-T H.812 – WAN interface ITU-T H.812.1 – Observation upload ITU-T H.812.2 – Questionnaires ITU-T H.812.3 – Capability exchange ITU-T H.812.4 – Authenticated persistent session
Part 3	HRN	Clause 9, Appendices E, F, L	Clause 12, Appendices III, IV, X	H.813 – HRN interface

History

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* To access the Recommendation, type the URL <http://handle.itu.int/> in the address field of your web browser, followed by the Recommendation's unique ID. For example, <http://handle.itu.int/11.1002/1000/11830-en>.

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.

Compliance with this Recommendation is voluntary. However, the Recommendation may contain certain mandatory provisions (to ensure, e.g., interoperability or applicability) and compliance with the Recommendation is achieved when all of these mandatory provisions are met. The words "shall" or some other obligatory language such as "must" and the negative equivalents are used to express requirements. The use of such words does not suggest that compliance with the Recommendation is required of any party.

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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) define a framework of underlying standards and criteria that are required to ensure the interoperability of devices and data used for personal connected health. They also contain design guidelines (DGs) that further clarify the underlying standards or specifications by reducing options or by adding missing features to improve interoperability.

Patient reported outcomes measures (PROMs) are increasingly needed to improve the cost effectiveness and quality of health services. This Recommendation defines design guidelines for the Questionnaire certified device class (CDC), whose function is to enable the interoperable exchange of PROMs (also known as questionnaires) across the WAN-IF of the Continua end-to-end architecture.

The questionnaires are represented according to the HL7 Implementation Guide (IG) for CDA R2 Questionnaire Form Definition (QFD) document [HL7 CDA QFD]. The QFD document captures the health survey questions or question sets to be administered to a patient. The QFD document enables the definition of questions for surveying the patient's perception on their health and the impact that any treatments or adjustments to lifestyle have had on their quality of life. QFD documents may carry a variety of clinical and non-clinical questions and branching logic in order to present the patient with a dynamic health survey for assessing health status including, but not limited to, the patient's functional, cognitive and physiological characteristics. Authors of the QFD documents may include information about disease management organizations, primary care physicians, health and fitness coaches, chronic condition monitors, post-acute and long-term care organizations.

The response to a questionnaire is then represented according to the HL7 Implementation Guide (IG) for CDA R2 Questionnaire Response (QR) document [HL7 CDA QRD]. Authors of the QR documents may include the patients who are under the care of disease management organizations, primary care physicians, health and fitness coaches, chronic condition monitors, and post-acute and long-term care providers or their agents.

For the exchange of QFD and QR documents, this Recommendation specifies and profiles the use of the HL7 hData record format and OMG hData REST Binding for RLUS. For security, this document further profiles the use of OAuth 2.0 and TLS v1.1.

This Recommendation is part of the ITU-T H.810 sub-series "H.810 Interoperability design guidelines for personal health systems". See [ITU-T H.810] for more details.

0.1 Organization

This Recommendation is organized in the following manner.

Clauses 0 to 5: Introduction and terminology – These clauses provide overview information which help in comprehending the remainder of the document.

Clause 6: Use cases – This clause provides motivating use cases for the Questionnaire certified device class (CDC) specified in this design guidelines document.

Clause 7: Behavioural models – This clause provides an overview of interactions between AHD and the WAN device that are specified by the Questionnaire CDC.

Clause 8: Implementation – This clause provides implementation specific details for the Questionnaire CDC.

Annex A:

Normative guidelines – This annex specifies the normative requirements that must be followed by the Questionnaire CDC.

0.2 CDC 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].

Recommendation ITU-T H.812.2

Interoperability design guidelines for personal health systems: WAN interface: Questionnaires

1 Scope

This Recommendation specifies design guidelines for the Questionnaire enabled AHD and Questionnaire enabled WAN CDCs that shall be followed. The design guidelines specify the testable requirements that must be implemented by the AHD in order to classify it as a Questionnaire enabled AHD. The Questionnaire enabled AHD shall be able to retrieve questionnaires from the WAN device and be able to validate that those questionnaires conform to the HL7 CDA R2 IG for QFD documents [HL7 CDA QFD]. In addition, the design guidelines specify testable requirements for a WAN device which details how a Questionnaire enabled WAN device shall respond to the requests from a Questionnaire enabled AHD and shall be able to validate that the QR documents conform to the HL7 CDA R2 IG for QR documents [HL7 CDA QFD].

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 (2015), *Interoperability design guidelines for personal health systems*.

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

3 Definitions

This Recommendation uses terms defined in [ITU-T H.810].

4 Abbreviations and acronyms

This Recommendation uses abbreviations and acronyms defined in [ITU-T H.810].

5 Conventions

This Recommendation follows the conventions defined in [ITU-T H.810].

6 Use cases

The use cases below are focused on the needs identified for retrieving questionnaires and posting questionnaire responses by patients.

6.1 Retrieve a list of questionnaires to-be-completed by a patient

Adam Everyman has heart failure and has recently been hospitalized for a decompensation event. As part of the discharge from the hospital he was enrolled in a telehealth programme that monitors his vitals at home and asks him regularly to provide subjective information about his condition.

The telehealth hub that is installed in Adam's home will regularly check with the telehealth server if there are any new questionnaires that Adam should fill in. When a questionnaire is scheduled for Adam by his care provider the telehealth hub will download the information about the questionnaire,

including the due date for completing it and a short message from Adam's care provider explaining what the questionnaire is for and who he can call in case of questions. The telehealth hub then shows on the start screen that a new questionnaire is available and when it is due for, and also enables Adam to check the note from his care provider related to this questionnaire.

6.2 Retrieve a specific questionnaire and let the patient fill it in

When Adam checks his telehealth hub in the morning he sees that there is a new questionnaire that he is asked to complete. The hub tells him that the questionnaire is about his heart failure symptoms and it also shows a brief note from his heart failure nurse where she writes that she hopes he has slept well and asks him to complete this symptom questionnaire preferably before lunch time. She also tells him to give her a call directly in case his symptoms are worse than normal.

Adam grabs a cup of tea and starts the questionnaire. He knows the questionnaire well as he is asked to fill in this questionnaire once per week. It asks about any signs of breathlessness or swelling that could signal a worsening of his heart failure. Luckily Adam feels pretty good and he can answer the questions by indicating that he has no problematic symptoms at this moment.

6.3 Upload the completed questionnaire to the patient record

Adam finishes answering the questions in the questionnaire and hits the "submit" button on his telehealth hub. The hub compiles his answers into a questionnaire response document and posts the document to Adam's health record at the telehealth server. The server analyses Adam's responses and determines that there are no problematic symptoms at this moment so there is no need to alert Adam's heart failure nurse. She can still review his answers if she would like to do so, for instance before she calls him for a regular checkup.

As Adam has now completed the questionnaire, the server will also remove this specific questionnaire from the list of questionnaires to-be-completed by Adam. The next time Adam's telehealth hub checks with the server for questionnaires to-be-completed it will not find this questionnaire in the to-do list anymore.

6.4 Retrieve a list of completed questionnaires from the patient record

As all completed questionnaires by Adam are stored in his health record at the telehealth server he can also see a list of all the questionnaires he has completed on his telehealth hub. This can be useful for him to be able to look back how he answered the symptom questionnaire a few weeks ago or review other questionnaires he has completed.

6.5 Retrieve a specific questionnaire response from the server

Adam may want to look back how he answered the symptom questionnaire a few weeks ago or review other questionnaires he has completed. He can also see a brief description of each completed questionnaire (title, description, link etc.) on his telehealth hub, hence he clicks on the link and the telehealth hub then retrieves the completed questionnaire response from the server.

7 Behavioural models

The following exchange mechanisms are specified for questionnaires and questionnaire responses:

- Retrieve a list of questionnaires to-be-completed from the server.
- Retrieve a specific questionnaire from the server.
- Create a new questionnaire response on the server.
- Retrieve a list of completed questionnaire responses from the server.
- Retrieve a specific questionnaire response from the server.

Creating a to-be completed questionnaire on the server is not defined in this specification as that is currently seen as taking place outside of this questionnaire service and the Continua E2E architecture.

The following diagram illustrates transactions related to the questionnaire use cases mentioned in this content profile.

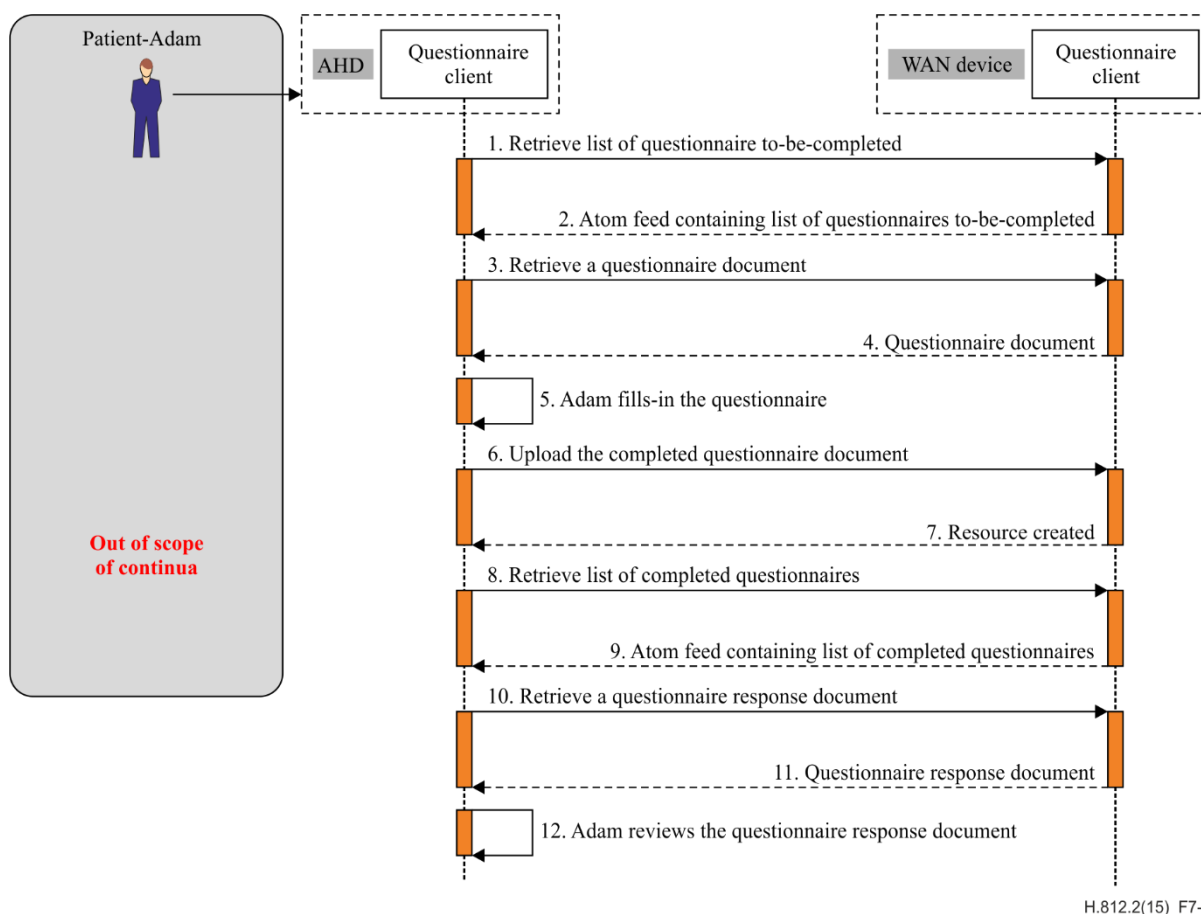


Figure 7-1 – Transactions between AHD and WAN device related to questionnaire use cases

8 Implementation

8.1 Content representation

The questionnaire and questionnaire response content is represented according to the following HL7 standards:

- HL7 Implementation Guide for CDA® Release 2.0: Questionnaire Form Definition Document, Release 1 [HL7 CDA QFD]
- HL7 Implementation Guide for CDA® Release 2.0: Questionnaire Response Document, Release 1 [HL7 CDA QRD]

The sample files for questionnaire and questionnaire response documents can be found in the submission packages for the above-mentioned standards.

8.2 Transport protocol

The Questionnaire-enabled AHD and WAN devices use hData over HTTP as a transport protocol for the exchange of Questionnaire and Questionnaire response documents across WAN-IF. For the detailed requirements on the use of hData over HTTP protocol between AHD and WAN devices, consult Annex A.

Annex A

Normative guidelines

(This annex forms an integral part of this Recommendation.)

Table A.1 – Normative guidelines for questionnaire-enabled AHD

Name	Description	Comments
Questionnaire_AHD_Content_Standard	Questionnaire-enabled AHD shall comply to the following standards for the representation of questionnaire and questionnaire response: <ul style="list-style-type: none"> – Questionnaire Form Definition Document [HL7 CDA QFD] – Questionnaire Response Document [HL7 CDA QRD] 	
Questionnaire_AHD_Transport_Standards	Questionnaire enabled AHD shall comply to the following transport standards: HL7 Version 3 Specification: hData Record Format, Release 1 [HL7 V3 HRF] OMG hData REST Binding for RLUS [OMG/hData BIND] OMG Retrieve, Locate, and Update Service (RLUS) Specification 1.0.1 [OMG/hData RLUS]	
AHD_Retrieve_List_Questionnaire	Questionnaire-enabled AHD shall use HTTP GET with the following URL for retrieving a to-be-completed questionnaire's list from the WAN device: <i>baseURL/continua/questionnaire</i>	See the use case in clause 6.1. For RLUS hData over REST transport, this is performed by performing an HTTP GET request without query parameters at the URL representing the patient's questionnaire hData root section path.
AHD_Questionnaire_dueDate	The atom entry element shall contain the dueDate extension element in the Continua namespace, the content of which shall conform to the "date-time" production in [IETF RFC 3339].	dueDate is used to indicate a precise moment in time before which the patient must complete the questionnaire. For further info on this element and content of the Atom feed entry element, consult Table I.1
AHD_Retrieve_Specific_Questionnaire	Questionnaire enabled AHD shall use the link element from the Atom feed entry to retrieve the actual questionnaire document and shall validate that it is a valid HL7 CDA R2 QFD document.	See the use case in clause 6.2. An example of the URL of a questionnaire that is in the questionnaire section of the hData record: <i>baseURL/continua/questionnaire/example.xml</i> For RLUS hData over REST

Table A.1 – Normative guidelines for questionnaire-enabled AHD

Name	Description	Comments
		transport, this is performed by performing an HTTP GET request without query parameters at this URL to retrieve the questionnaire document.
AHD_Post_Questionnaire_Response	Questionnaire enabled AHD shall use HTTP POST with the following URL for posting questionnaire response to the WAN device: <i>baseURL/continua/questionnaireResponse</i>	See the use case in clause 6.3.
AHD_Retrieve_List_Questionnaire_Response	Questionnaire enabled AHD shall use the following URL for retrieving completed questionnaires list from the WAN device: <i>baseURL/continua/questionnaireResponse</i>	See the use case in clause 6.4. For RLUS hData over REST transport, this is performed by performing an HTTP GET request without query parameters at the URL representing the patient's questionnaire response hData path.
AHD_Retrieve_Specific_Questionnaire_Response	Questionnaire enabled AHD shall use the link element from the Atom feed entry to retrieve the actual questionnaire response document and shall validate that it is a valid HL7 CDA R2 QR document.	See the use case in clause 6.5. For further info on Atom feed entry element consult Table I.2. As a result of AHD_Retrieve_Questionnaire_Response, Questionnaire-enabled AHD receives ATOM feed. An example of the URL of a questionnaire response that is in the questionnaire response section of the hData record: <i>baseURL/continua/questionnaireResponse/abc123.xml</i> For RLUS hData over REST transport, this is performed by performing an HTTP GET request without query parameters at this URL to retrieve the questionnaire response document.

Table A.2 – Normative guidelines for Questionnaire-enabled WAN device

Name	Description	Comments
WAN_Questionnaire_Content_Standard	<p>Questionnaire-enabled WAN device shall comply to the following standards for the representation of questionnaire and questionnaire response:</p> <ul style="list-style-type: none"> – Questionnaire Form Definition Document [HL7 CDA QFD] – Questionnaire Response Document [HL7 CDA QRD] 	
WAN_Questionnaire_Transport_Standards	<p>Questionnaire-enabled WAN device shall comply to the following transport standards:</p> <ul style="list-style-type: none"> – HL7 Version 3 Specification: hData Record Format, Release 1 [HL7 V3 HRF] – OMG hData REST Binding for RLUS [OMG/hData BIND] – OMG Retrieve, Locate, and Update Service (RLUS) Specification 1.0.1 [OMG/hData RLUS] 	
WAN_Questionnaire_Root	<p>Questionnaire-enabled WAN device shall include the following elements for questionnaire content in the root.xml file:</p> <ol style="list-style-type: none"> 1.profile <ol style="list-style-type: none"> a. id="questionnaire" b. reference= http://handle.itu.int/11.1002/3000/hData/Questionnaire/2015/01/H.812.2.pdf 2.section <ol style="list-style-type: none"> a. path=" questionnaires" b. profileID= "questionnaire" c. resourceTypeID=" questionnaire" 3.resourceType <ol style="list-style-type: none"> a. resourceTypeID=" questionnaire" b. reference="http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=116" c. representation <ol style="list-style-type: none"> i. mediaType="application/xml" 	
WAN_Questionnaire_Response_Root	<p>Questionnaire-enabled WAN device shall include the following elements for questionnaire response content in the root.xml file:</p> <ol style="list-style-type: none"> 1.profile <ol style="list-style-type: none"> a. id="questionnaireResponse" b. reference=http://handle.itu.int/11.1002/3000/hData/Questionnaire/2015/01/H.812.2.pdf 2.section <ol style="list-style-type: none"> a. path="questionnaireResponses" b. profileID="questionnaireResponse" c. resourceTypeID="questionnaireResponse" 3.resourceType <ol style="list-style-type: none"> a. resourceTypeID="questionnaireResponse" b. reference="http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=117" c. representation <ol style="list-style-type: none"> i. mediaType="application/xml" 	

Table A.2 – Normative guidelines for Questionnaire-enabled WAN device

Name	Description	Comments
WAN_Questionnaire_Response_Validate	Questionnaire enabled WAN device shall validate the questionnaire response document that it is a valid HL7 CDAR2 Questionnaire response document and send the HTTP 201 as a response if it is a valid document.	
WAN_Creation_Questionnaire	Questionnaire enabled WAN device shall not support the creation of new questionnaire record via the hData interface and shall return HTTP 405 Method Not Allowed as a response to HTTP POST request on questionnaire section path.	One record covers a single questionnaire or questionnaire response document. For the creation of a new questionnaire response document consult AHD_Post_Questionnaire_Response guideline.
WAN_Modification_Questionnaire_Response	Questionnaire enabled WAN device shall not support the modification of an existing questionnaire or questionnaire response record and shall return HTTP 405 Method Not Allowed as a response to HTTP PUT request on questionnaire or questionnaire response section path.	
AHD_Delete_Questionnaire_Response	Questionnaire enabled WAN device shall not support the deletion of an existing questionnaire or questionnaire response record and shall return HTTP 405 Method Not Allowed as a response to HTTP DELETE request on questionnaire or questionnaire response section path.	

Appendix I

ATOM feed information elements

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

The following ATOM feed child elements of the entry element have a specific usage for the purpose of questionnaires.

Table I.1 – ATOM feed child elements for questionnaires

Element	Usage
author	Person construct that indicates the person who requested that the patient complete this questionnaire.
Id	Must be a globally unique identifier, which must be included in the questionnaire response document (InFulfillmentOf field) that is created upon completing the referenced questionnaire, so that the server knows the relationship between the request to complete the questionnaire document and the posted questionnaire response document.
Title	Title of the questionnaire.
Summary	More detailed statement on the request to complete this questionnaire, e.g. "Dear Mr. Everyman, Could you complete this survey on heart failure symptoms before lunch time? In case your symptoms are worse than normal, please call me directly. Have a nice day. Best regards, Nurse Betty"
link	Reference to the questionnaire document which must be a valid HL7 CDAR2 Form Definition IG document. The link can be relative if the questionnaire can be retrieved via the questionnaire section of the hData record, but it can also be an absolute link if the questionnaire is located outside of the current hData record, e.g. at https://www.example.org/surveys/QoL.xml
dueDate	This element is not part of the normal atom namespace and is an extension created by Personal Connected Health Alliance for a questionnaire use case. It is used to contain the due date for completing the questionnaire by the patient and can be used by the SC to convey a sense of urgency to the patient. The content shall conform to the "date-time" production in [RFC3339]. In addition, an uppercase "T" character shall be used to separate date and time, and an uppercase "Z" character shall be present in the absence of a numeric time zone offset. The dueDate element is defined in the Continua namespace. The atom:entry element in "The Atom Syndication Format" schema shall then refer to the dueDate element in the following way: <pre><xs:element ref="continua:dueDate" minOccurs="1" maxOccurs="1"/></pre> The schema for defining the continua:dueDate element shall then contain the following statement: <pre><xs:element name="dueDate" type="atom:dateTimeType"/></pre>

Table I.1 – ATOM feed child elements for questionnaires

Element	Usage
	The content of the dueDate is represented in the same manner as date-time is represented in "The Atom Syndication Format" schema. As an example consult the "The Atom Syndication Format" schema defined here [b-ATOM Schema].

The following ATOM feed child elements of the entry element have a specific usage for the purpose of questionnaire responses.

Table I.2 – ATOM feed child elements for questionnaire responses

Element	Usage
author	Person construct that indicates who provided the information in the questionnaire response i.e. who completed the questionnaire.
Title	Title of the original questionnaire to which this questionnaire response belongs.
Link	Reference to the questionnaire response document which must be a valid HL7 CDAR2 Questionnaire Response IG document. The link shall be relative and the questionnaire response document shall be in the questionnaire response section of the hData record.
Published	The published element shall be set to the data/time at which the questionnaire response document was posted to the server.

I.1 Information for questionnaire in the root.xml

```

<profile>
  <id>questionnaire</id>
  <reference>
http://handle.itu.int/11.1002/3000/hData/Questionnaire/2015/01/H.812.2.pdf
  </reference>
</profile>
<section>
  <path>questionnaires</path>
  <profileID>questionnaire</profileID>
  <resourceTypeID>questionnaire</resourceTypeID>
</section>
<resourceType>
  <resourceTypeID>questionnaire</resourceTypeID>

<reference>http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=116</reference>
  <representation>
    <mediaType>application/xml</mediaType>
  </representation>
</resourceType>

```

I.2 Information for questionnaire response in the root.xml

```
<profile>
  <id>questionnaireResponse</id>

  <reference>http://handle.itu.int/11.1002/3000/hData/Questionnaire/2015/01/H.812.2.pdf </reference>
</profile>
<section>
  <path>questionnaireResponses</path>
  <profileID>questionnaireResponse</profileID>
  <resourceTypeID>questionnaireResponse</resourceTypeID>
</section>
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  <reference>
http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=117</reference>
  <representation>
    <mediaType>application/xml</mediaType>
  </representation>
</resourceType>
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Bibliography

See [ITU-T H.810 (2015)] for a list of non-normative references and publications that contain further background information.

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