



PICNIC

PROFESSIONALS AND CITIZENS
NETWORK FOR INTEGRATED CARE

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Reporting Experiences from Using the HL7 Clinical Document Architecture in the PICNIC

1. Introduction

Abstract

This paper reports on a framework for the development of a clinical messaging services by the PICNIC EU-funded R&D project, based on the principles of open standards, components reuse, interoperability and intra-regional harmonization. Specific issues that will be discussed are: (a) creation of a regional middleware service to support the exchange of clinical messages, (b) development of clinical messages for community pharmacy reimbursement based on HL7's Clinical

Document Architecture, and (c) document assembly based on the clinical & administrative context.

Paper Outline

The paper covers the following topics:

- 1) Developing a harmonized interregional CDA specification, based on HL7 CDA Level 1 Release 1.0
- 2) Developing integrated clinical messaging services in the General Medical Services Board in Ireland for pharmacy reimbursement, based on: open standards, component reuse, interoperability
- 3) CDA document assembly by FORTH in Crete, based on the clinical & administrative context.
- 4) The development of a collaboration service in Denmark, utilizing CDA messages.

2. Harmonised CDA Specification

The CLINICAL_DOCUMENT_HEADER for the harmonised PICNIC CDA level 1 header message includes all of the elements in the table in section 3, which are derived from the HL7 Clinical Document Architecture (CDA) Level 1 standard. It includes those elements within the overall CDA level 1 standard that were considered relevant to the participating PICNIC regions in relation to their PICNIC prototypes.

The task 6.2 Clinical Messages Specification of the PICNIC workpackage 6 (Common Components) was started during October 2001. The activity is based on the previous work in the PICNIC-project and the following deliverables:

- Executive Summary Clinical Messages 3rd Nov 2000
- D4.1 Harmonised description of Clinical Message service
- D4.2 Functional Specification and Minimum Data Set
- Task 6.1 Standard for Component Specification – Clinical Messages

The initial document was taken as an example from the Macropilot-project in Finland and sent to partners in October 2001 together with relevant documents concerning the CDA standard of ANSI and other related information.

The organization mentioned in the cover-page (FORTH, FUNEN, GMS) produced their own documents based on the Macropilot specification v. 1.92 :

- GMS: Pharmacy Reimbursement Messaging Component Specification
- FUNEN: Collaboration Messaging Component Specification
- FORTH: Clinical Messages for Teleconsultation (CDA-header Specification)

These documents were discussed and harmonised in the PICNIC-workshop in Crete on 28th November 2001. The PICNIC regions decided by themselves about the granularity of the information needed; i.e. the values of the attributes of the elements (including coded values with extension, CWE). The detailed RIM model can be viewed from http://www.hl7.org/library/data-model/RIM/modelpage_mem.htm .

Senders and receivers are considered as service actors. Therefore one can use the "provider" and/ or "service_actor" XML elements. Those elements were discussed and considered optional in the specification. Note that considering an element 'optional' means that a regional service may or may not use it, as they choose, but interoperable services should understand it. Note also that according to the CDA

specification "service_actor" may be a person or an organization, while "provider" is a person. In the "original" idea of the CDA, the sender and recipient elements are expressed in the local headers.

Why use CDA in PICNIC?

CDA is a standard to describe the structures of clinical documents. Level 1 sets a requirement for the structure of the header. It sets (practically) no requirements for the body. To transfer these structured level 1 documents one can use XML (Extensible Markup Language). To display (or print) these in different formats you can use DTD's (Data Type Definitions) or style sheets (XSL).

Today there are a number of internationally (partly) competing standards relating to message content. Some of these are tied to a certain technology, i.e. do not allow the separation of content from technology. The earliest of these standards is Edifact which is today being used extensively also for health care messaging. There are several Edifact messages available in CEN TC251. Lately this committee has also decided to separate content from technology and does not specify Edifact as the only implementation technology. Since the mid-90s CEN TC 251 gradually developed and refined an UML-based (Unified Modelling Language) domain information model methodology that also heavily influenced Health Level Seven's V3 methodology. Furthermore, today CEN and HL7 work closely together in the messaging area. HL7 V2.x is another example of a widely used message standard that does not separate content from the envelope.

True separation is now the accepted norm and work is proceeding on those lines first to set up international standards for content and then to specify implementations with various technologies. HL7's V3 with its generic Reference Information Model is the current goal that is being pursued not only by US but also by several HL7 affiliates across the globe representing both local industries and users. Additionally, as mentioned above CEN TC251 is heavily involved in this as well. Naturally, there are some that fear that this will lead to a standard set by the Americans. As in all volunteer standards work, the outcome is defined by those who participate. On the other hand, a standard is only used if there are benefits in using it. I.e. vendors and users in Europe will not be using standards that they find obstructive, difficult or useless.

Anyway, V3 is not here yet. The 1st committee level ballot of this autumn has been concluded and the 2nd committee level ballot is planned for February 2002. If that meets with enough approval a membership level ballot is expected in late 2002 and if that leads to approval then V3 might be accepted around the end of 2002 earliest. Clearly V3 is therefore out of the scope of PICNIC given its piloting timescales. What else? In CEN the DIM (Domain Information Model) approach deriving message content from domain information models with a few messages is available. In the same style is HL7's MDF & RIM uses. These are clearly converging. But this is not available as yet for PICNIC to deploy.

So what can be used that allows PICNIC development to follow the general principle of content separated from technology and also offers a path to migrate to the standards being currently developed? The obvious answer is CDA Level One for content and XML as the technology.

Today CDA Level One is an HL7 approved standard, also with ANSI approval. CDA is intended as a framework (architecture) for describing the structure of clinical documents. It focuses on the structuring of clinical documents. Future extensions (Level 2 and Level 3) will provide more guidance / requirements for the structure of clinical documents. The standard is based on the notion that "all medical information" is stored and read as documents. CDA seeks to bring structure to these documents in order to make them interoperable. Level 1 does not refer to the V3 RIM. The future extensions Level 2 and 3 will. I.e. CDA will be "RIM compliant".

XML is used to describe the structure of clinical documents. XML can also be used to create different visual renderings of the contents for various purposes.

Presently, there is no point (nor possibility) to require PICNIC regions to comply with RIM. Instead, for the time being, it makes sense to require that the contents that will be exchanged in the form of messages or shared in the context of a shared teleconsultation folder complies with the requirements of CDA Level 1. Why, because :

CDA Level 1 is only concerned with the structure, not the contents with the exception of the header for which there are mandatory requirements. Having a header complying to CDA "does not hurt anyone". Everyone in PICNIC has to provide info about the contents of any clinical document. Hence everyone will have to provide a header. Why not agree that this header information is structured in accordance with CDA Level 1? CDA allows documents to be exchanged with XML which everyone seems to want anyway. XML implementations are the goal for all concerned. Again, the same argument why not agree to structure the header in a common way? CDA offers a migration path towards full RIM compliance once V3 is available.

Risk assessment

There are no risks except the effort that is required for partners to become acquainted with the CDA standard and the way it can be implemented. As far as one can presume, FORTH has already acquired the know-how to deploy CDA. The same applies for Macroppilot. Funen and GMS have to "come on board" which will require an effort, i.e. man hours. But past experience in Finland is that this is not an exceptionally difficult task. It just requires the effort to go through the standard.

3. CDA Developments in GMS(P)B

GMS(P)B Health Information Network

The General Medical Services (Payments) Board (GMS(P)B), validates claims and processes payments to all General Practitioners (GPs), Pharmacists and Dentists (collectively referred to as ‘contractors’) in Ireland, in relation to services provided to eligible persons (determined by means testing/age) under the General Medical Services Scheme and a range of other healthcare related funding schemes.

The GMS (Payments) Board (GMS) currently administers a number of Community Drug (cost subsidisation) schemes, including the Drug Payments Scheme (DPS) where households within Ireland pay a fixed monthly amount for prescription drugs.

GMS is seeking to provide the 1,200 pharmacists (and later another 3,300+ contractors) access to its back end patient index systems. GMS has therefore developed an architecture that will allow for connection of these contractors to its back end systems. The architecture has the following characteristics:

- All communication between GMS and outside bodies, which contains personal medical data, must be encrypted.
- Mutual authentication between GMS and outside organisations is required.
- The proposed architecture must scale to handle the connection of 5,500+ external contractors to the GMS systems.
- The proposed architecture must be resilient.

A three-tier architecture, based on the interim PICNIC Architecture, has been used, as shown in Figure 1 below.

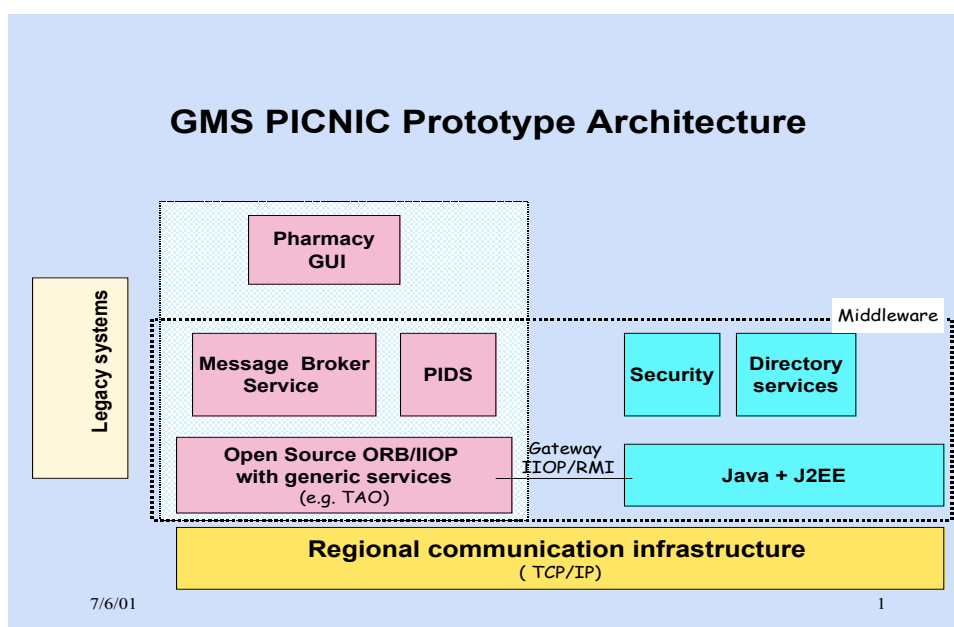


Figure 1: GMS PICNIC Prototype Architecture

GMS Middleware Components

The GMS contribution to the PICNIC project includes the development of a 'Pharmacy Patient Validation & Electronic Reimbursement' prototype, based on the use of open source common components. The GMS PICNIC prototype includes the provision of a PIDS Access/Messaging Component and a 'PIDS Server' component. Messaging between the components is handled via HL7 CDA based messages sent over a Microsoft based network.

The prototype is based on the use of two 'common components' that are installed on the pharmacy application systems and in the middleware that interfaces to the back-end patient index system at GMS. The two common components are:

- A 'PIDS Access/Messaging' component, and a
- 'PIDS Server' component.

The GMS PIDS Access/Messaging Components resides on the pharmacist PC and is integrated with the pharmacy application system. The PIDS Server component is based on the OMG PIDS specification and is integrated into the GMS middleware. It implements the 'Simple PIDS' interface, as defined in the OMG specification, (in so far as it can be supported by the underlying CCEI PIDS database). The middleware technical architecture for the GMS PICNIC prototype is illustrated at Figure 2 below, showing the use of the two common components.

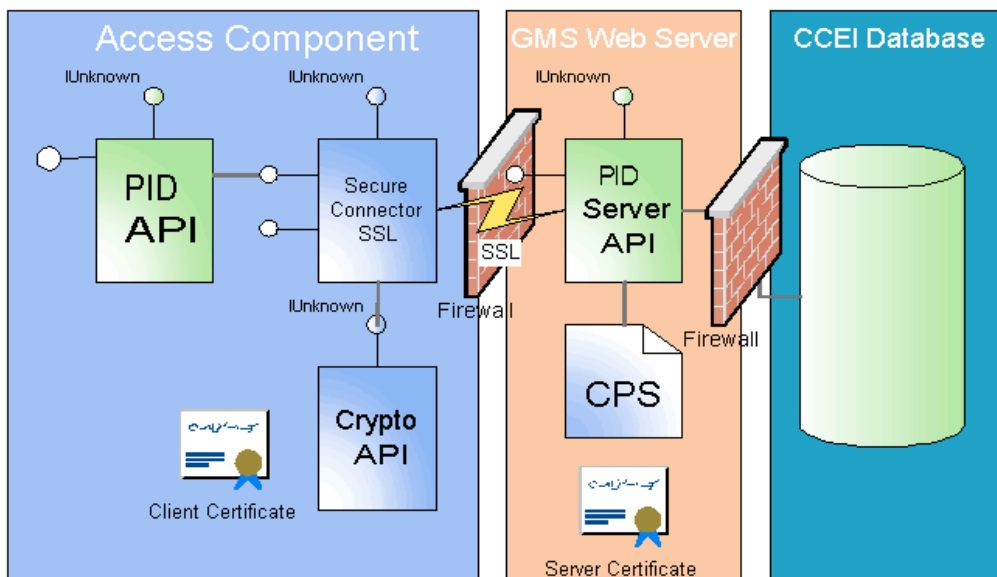


Figure 2: GMS Common Components

The PIDS Access/Messaging Components provides the pharmacy application system vendors with an API that can be used to implement the following functions:

- Establish a secure (i.e. encrypted) network link to GMS where a pharmacist's system and GMS mutually authenticate each other.
- Transmit swipe card ID data to GMS and receive the resulting response from GMS.

- Send messages and upload/download files to and from GMS. The prescription reimbursement files and the corresponding exception files are formatted using the PICNIC XML/CDA message format.

Once a pharmacy application vendor has integrated the PIDS Access common component into the pharmacy application, the application will be able to access the back end GMS systems to:

- Verify the identity of a client, his/her eligibility under the DPS scheme and the amount spent on prescriptions to date in the current month.
 - Update the central GMS system with the value of a prescription issued to a client.
 - Upload prescription reimbursement files to GMS and download the corresponding exception file from GMS.

The PIDS Server component is implemented using Enterprise Java Beans (EJBs) running on a WebLogic application server. The servlet runs on the WebLogic Web Server, which is included in the application server.

The PIDS Server component is based on the OMG PIDS specification. It implements the 'Simple PIDS' interface, as defined in the OMG specification, in so far as it can be supported by the underlying CCEI PIDS database. For example, the CCEI (Central Client Eligibility Index) at GMS only supports the 'INVALID', 'PERMANENT' and 'DEACTIVATED' IDstates defined in the OMG PIDS specification. (NB. The 'UNKNOWN' and 'TEMPORARY' IDstates do not exist on the CCEI database).

The processing performed on the WebLogic Application Server is as follows:

- The servlet receives an input XML message from the PIDS Access/Messaging component.
- The servlet/EJB parses and validate the incoming XML message. It will then extract the parameters and use them to make a call to the PIDS Server component.
- The PIDS Server component is implemented using EJBs (Enterprise Java Beans) on WebLogic, running on Linux. The PIDS Server component accesses the CCEI database to retrieve the information required. The data returned from the PIDS Server component is formatted by an EJB/servlet into an XML output message, which is returned to the remote Windows application via the PIDS Access /Messaging component.

PICNIC interfaces are presented in IDL format. The PIDS Server component is based upon the OMG (Object Management Group) PIDS Specification and has been developed using Enterprise Java Beans (EJBs) using the WebLogic application server. EJB was selected as the technology to implement the PIDS Interface, as it is one of the most widely used component technologies in the market today. This approach promotes two PICNIC goals, which is to increase both the availability and use of open source software within the health sector in the EU. Note: while the PIDS Server EJBs will be implemented on WebLogic, they can also be deployed on an open source application server such as JBoss.

Creating the Clinical Message

The clinical messages that are sent over the infrastructure described above are formatted via CDA and/or XML. The clinical message to support community pharmacy reimbursement in the GMS PICNIC prototype is composed of two parts:

- A header record, conformant to CDA level 1
- A body record, based on the EDIFACT' MEDRUC' reimbursement message format, translated into a CDA conformant body message.

The CLINICAL_DOCUMENT_HEADER for the GMS PICNIC CDA level 1 header message includes all of the elements in the table below, which are derived from the HL7 Clinical Document Architecture (CDA) Level 1 standard. It includes all of those elements within the overall CDA level 1 standard that were considered relevant to the participating PICNIC regions in relation to their PICNIC prototypes.

ELEMENT	MEANING	MANDATORY?
Clinical_document_header	Root element of header part of document	Yes
Id	Identifies the XML-document message	Yes
Set_id	Identifies the XML-document header	Yes
Version_nbr	Version of document applicable	No
Document_type_cd	Classification of document, eg, DPS claim	Yes
Origination_dttm	Origination date of document header	Yes
Copy_dttm	Time the document leaves the document system	No
Confidentiality_cd	Level of document confidentiality	Yes
Fulfills_order	References an 'order' document, eg, a script, to which the defined document is a response	No
Patient_encounter	Unique global id number for the 'event'	No
Authenticator	Person that verifies the accuracy of the document	No
Legal_authenticator	Specifies the legal document authenticator	No
Originating_organization	Agency sending the message, ie, the pharmacy	Yes
Provider	Healthcare professional\or agency involved in (prescribing) the service described in the document, eg, GP or hospital doctor	Yes
Service Actor	Any other party involved, eg, GMS for claims	No
Patient	Patient to whom document relates	Yes

Local_header	Any other locally defined data, eg, key parameters	No
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Every element has its own sub-structure composed of either child elements and/or attributes (as set out in the CDA standard document – ref 1). The sub-structures of the elements as defined in the GMS Pharmacy prototype are described below. (See also Appendix 1 ‘CDA Header DTD’ and Appendix 2 ‘Example XML’).

Id

The ‘Id’ element identifies the XML document message, via a globally-unique instance identifier. The value for the identifier is held in an “EX” attribute. This is generated from a combination of date, time, originating computer id, and creator id no.

Example:

```
<Id EX="1203200204042299990001"/>
```

Set_id

The ‘Set_id’ element identifies the XML-document header, via an identifier that remains constant across all document revisions/versions. The value for the identifier is held in an “EX” attribute. (NB. This identifier is managed by the source system’s document management software. It is not significant in the context of the GMS Pharmacy Reimbursement pilot).

Example:

```
<Set_id EX="B"/>
```

Version_nbr

The ‘Version_nbr’ element identifies the version of the document used, eg, version 1.0, version 1.1. The Version_nbr element has an attribute, ‘V’, which holds the version no. (NB. This version number is managed by the source system’s document management software. It is not significant in the context of the GMS Pharmacy Reimbursement pilot).

Example:

```
<Version_nbr V="1.2"/>
```

Document_type_cd

The ‘Document_type_cd’ element describes the document classification, eg, ‘DPS claim’ or ‘Hi-tech claim’. The Document_type_cd element has two attributes, ‘V’ (value) and ‘DN’ (description).

The values of the ‘V’ attribute of the Document_type_cd element, and the associated ‘DN’ attribute, are:

- DP Drugs Payment Scheme
- GM GMS (Regular)
- GR GMS (Repeat)
- LT Long Term Illness
- EU European Union
- HT High Tech
- EM Hospital Emergency
- HA Health Act Amendment
- SO Doctor Stock Order
- DE GMS Dental Scheme
- HD Hardship Scheme
- ME Methadone Scheme
- DC Drugs Cost Subsidisation Scheme.

Example:

```
<Document-type_cd V= "DP" DN="Drugs Payment Scheme"/>
```

Origination_dttm

The 'Origination_dttm' element has a 'V' attribute, which defines the origination date (ie, date of creation of the document) of the document header in the format 'YYYY-MM-DD-HH-MM-SS' (NB. The use of the 'HH-MM-SS' part of the field is optional).

Example:

```
<Origination_dttm V="2001-12-07"/>
```

Copy_dttm

The 'Copy_dttm' element has a 'V' attribute which defines the transmission date (ie, the date that a copy of the document was sent from the originating device to another device) of the document header in the format 'YYYY-MM-DD-HH-MM-SS' (NB. The use of the 'HH-MM-SS' part of the field is optional).

Example:

```
<Copy_dttm V="2001-12-07"/>
```

Confidentiality_cd

The 'Confidentiality_cd' element defines the level of document confidentiality.

The Confidentiality_cd element has three child elements, 'ID', 'V' and 'DN'.

The values of the ID attribute of the Confidentiality_cd element are:

- 'CONF1'
- 'CONF2'
- 'CONF3'
- 'CONF4'.

The values of the V attribute of the Confidentiality_cd element are:

- 'S'
- 'T'
- 'I'
- 'N'.

The corresponding values of the 'DN' attribute are:

- 'Information for which the patient seeks heightened confidentiality'
- 'Information not to be discussed with patient except through practitioner'
- 'Individual access to persons who are mentioned as actors'
- 'Normal'.

(NB. For the GMS Pharmacy Reimbursement pilot, the respective values will be 'CONF4', 'N' and 'Normal').

Example:

```
<Confidentiality_cd ID="CONF4" V="N" DN="Normal"/ >
```

Fulfills-order

The 'Fulfills_order' element defines the source document in the case of an 'order' for services, to which this document is (or is part of) the response, eg, a prescription, for which the document defined by the DTD is the result. The Fulfills_order element has two child elements, 'Fulfills_order.type_cd' (with a 'V' attribute that is always "FLFS"), and 'order', which has as 'id' element with an 'EX' attribute, which can be used to hold the order code number to which the defined document is a response. (NB. For the GMS pilot, order code number will always be set to 'null', i.e., "9999").

Example:

```
< Fulfills_order>
```

```
  < Fulfills_order.type_cd V="FLFS"/>
```

```
<Order>< id EX="0000"/></Order>
</Fulfills_order>
```

Patient_encounter

The 'Patient_encounter' element refers to information about the events relating to the delivery of a care package to a patient, including a child 'id' element with an 'EX' attribute which holds a unique global id number for each 'patient event'.

(NB. For the GMS pilot, this code will be set to null, i.e., "0000").

Example:

```
<Patient_encounter>
  <id EX= "0000"/>
</Patient_encounter>
```

Authenticator

The 'Authenticator' element defines the person who can verify the authenticity and/or accuracy of the document. The Authenticator element has two child elements, 'Authenticator.type_cd' (with a 'V' attribute which is always "SPV") and 'Signature-cd', with a 'V' attribute, which can be used to hold a code which shows that an electronic signature held on file ('S'), or is required to be provided for this document ('X'). (NB. For the GMS pilot, the 'V' attribute will always be set to "S").

Example:

```
<Authenticator>
  < Authenticator.type_cd V="SPV"/>
  <Signature_cd V="S"/>
</Authenticator>
```

Legal_authenticator

The 'Legal_authenticator' element defines the person who is legally responsible for the document and can attest to its authenticity/accuracy. Legal_authenticator has two child elements, 'Legal_authenticator.type_cd' (with a 'V' attribute which is always "SPV") and 'Signature-cd', with a 'V' attribute which can be used to hold a code which shows that an electronic signature is held on file ('S') or is required to be for this document ('X').

Example:

```
<Legal_authenticator>
  < Legal_authenticator.type_cd V="SPV"/>
  <Signature_cd V="S"/>
</Legal_authenticator>
```

Originating_organization

The 'Originating_organization' element identifies the sending organization from which the message originated, ie, in the case of pharmacy reimbursement, the pharmacy sending the claim.

The Originating-organization element has a number of child elements, including 'Originating_organization.type_cd', with a 'V' attribute (always "CST"), and child elements: 'id', with an 'EX' attribute (GMS pharmacy code) and 'Organization.nm', with a 'V' attribute.

Example:

```
<Originating_organization>
  <Originating_organization.type.cd V="CST"/>
  <Organization>
    <id EX="14523"/>
    <Organization.nm V="James Street Pharmacy"/>
```

```
</Organization>
</Originating_organization>
```

Provider

The 'Provider' element identifies the type of relevant health care professional/agency (eg, a GP or hospital doctor).

The Provider element has two child elements, 'Provider.type_cd' (with a 'V' attribute, value always "CON") and 'Person'. The Person element has a child 'id' element, with an 'EX' attribute, which can hold the relevant reference number (ie, GMS GP code).

Example:

```
<Provider>
  <Provider.type_cd V="CON"/>
  <Person>
    <id EX="21524"/>
  </Person>
</Provider>
```

Service_actor

The 'Service_actor' element defines any other person/agency involved in the patient encounter, ie, a party who is not either the patient, or the provider or the originator, eg, GMS in the case of a pharmacy claim document sent from a pharmacist.

The Service_actor element has a child element, 'Service_actor.type-cd', with a 'V' attribute, which is always "GMS".

Example:

```
<Service_actor>
  <Service_actor.type_cd V="GMS"/>
</Service_actor >
```

Patient

The 'Patient element' identifies the patient to whom the document relates. The Patient element has a number of child elements, including 'Patient.type_cd' (with a 'V' attribute which is always "PATSBJ") and 'Person', which has in turn a child element of attribute of 'id' with an 'EX' attribute.

The value of the 'EX' attribute of the id element of the Person element is the identity number of the patient (ie, the unique patient identity number, PPSN/CCEIN).

Example:

```
<Patient>
  <Patient.type_cd V="PATSBJ"/>
  <Person>
    <id EX="1234567890"/>
  </Person>
</Patient>
```

Local_header

The 'Local_header' element provides any additional key parameters, eg, an e-mail address for inquiries. The Local_header element has a child element, 'Local_attr'. The Local_attr element has two attributes, 'Name' and 'Value'.

The value of the 'Name' attribute of the Local_attr element of the Local_header element is the name of the key parameter.

The value of the 'Value' attribute of the Local_attr element of the Local_header element is the the value of the key parameter.

Example:

```
<Local_header>  
  <Local_attr Name="Key1" Value="Value1"/>  
</Local_header>
```

Reimbursement Message

The GMS Reimbursement message document includes a header and a body. The header conforms to the CDA level 1 structure (see above). The Reimbursement message body has been defined using the ‘Medruc’ format as a starting point (NB, as only CDA level 1 conformance is being sought, the semantic content of the body is not prescribed by the CDA standard).

The structure of the CDA body message is based on the EDIFACT ‘MEDRUC’ standard message format, as documented in the GMS MEDRUC specification version 1.2 of 7th September 1999. It should be noted, however, that some fields from the MEDRUC specification have been removed from the CDA body message, as they are either duplicated in the CDA header, or are redundant.

The fields that have been removed and inserted in the header are: Pharmacy number, Scheme code, Pharmacy Version number, Patient Ref number and Prescriber number. The fields that have been removed as redundant are: Pharmacy name, Pharmacy address, GP Name, GP Address, Patient Name, and Patient Address.

In addition, some fields have been added to those included within the MEDRUC format message, in order to provide the equivalent information to the existing GMS Electronic Claims file specification. The fields which have been added are: Number of items, Number of Regular forms, Number of Exception forms, Form number, Line number and Line type.

The fields on the reimbursement claims are grouped into a number of ‘main elements’. These elements are shown in the table below:

Element	Description
ADMINISTRATIVE	Administrative information about the script.
ORDINATION	Information about the line item on the script & the drugs dispensed.
REIMBURSEMENT	Information about the claim.
MSG-INFORMATION	Information relation to the electronic transfer of data.

Each of these elements have been defined as elements in the CDA body record.

4. CDA developments in FORTH

Introduction

The Institute of Computer Science, FORTH, has been facilitating technology developments in HYGEIAnet, the regional health telematics network of Crete. A significant objective in HYGEIAnet is the deployment and evaluation of information systems that support an organization's daily activities while at the same time facilitating collaboration with other organizations, healthcare professionals, and patients. Within the organization, an integration strategy building on a common application framework enables seamless inter-working of reusable components, middleware services, and subsystems that provide specialized functionality [1]. At a regional level, information systems contribute information to the IEHR (Integrated Electronic Health Record) [2] and promote collaborative information sharing in the context of telemedicine services.

Clinical information systems in HYGEIAnet are part of the IEHR federation. The IEHR provides access to all information related to the electronic health record of an individual. Thus, although each healthcare facility is autonomous and devoted to the delivery of a particular set of services, different healthcare facilities offering complementary services or different levels of expertise are able to get a complete picture of an individual's medical history. In IEHR, along with face-to-face clinical encounters, the so-called teleconsultation folders (TCFs) are indexed. TCFs record information regarding the interaction of healthcare professionals as part of a second opinion request. Clinical information recorded and shared in a TCF includes clinical documents in CDA, diagnostic imaging examinations in DICOM and resting ECGs in the SCP-ECG standard format.

The clinical document architecture has been deployed in HYGEIAnet to facilitate the sharing of EHR data in remote cardiology and radiology consultation. Teleconsultation services adhere to stringent requirements for security, accountability, accessibility, and integration based on the clinical context. CDA Level 1 has been used in teleconsultation services to enable sharing of digitally signed clinical documents. Main considerations in the design of the teleconsultation system are efficiency and effectiveness. These were reflected in the support of clinical protocols and guidelines and the integration to clinical information systems based on the clinical context.

The PICNIC project has furthered this experience by placing under consideration, important issues relevant to design and deployment of interregional collaboration services.

Integrated teleconsultation services in HYGEIAnet

Remote consultation involves requesting a second opinion regarding a particular clinical episode. Teleconsultation may involve community doctors, or remote healthcare centers consulting a district or regional cardiology department. As an example drawn from cardiology, consider a General Practitioner (GP) at the remote healthcare center. The GP conducts a clinical examination of the patient, records a digital 12-lead ECG, and possibly orders some relevant laboratory exams. All this

information is stored in the local EHR system. In case of a suspicious ECG recording, instead of transferring the patient to a central hospital, the GP may request a second opinion from a telemedicine center. Based on the suspected medical problem, the GP selects the most appropriate service option. Then, transparently, based on the clinical context the explicitly or implicitly known patient and encounter identification are used to retrieve and auto-complete as many fields of the request template as possible.

Special filters may be used to retrieve and structure terminology, resource, or prescription data in the teleconsultation request template. Next, XSL templates personalize the presentation of the clinical document template according to the preferences of the GP. The GP reviews the clinical document template, selects one of the available telemedicine centers and/ or experts retrieved from the regional resource service, and adds further information or comments. A CDA document is constructed, digitally signed by the GP, and submitted to the selected telemedicine center as part of a teleconsultation request.

The teleconsultation request including the CDA document and linked ECG in SCP-ECG format [3] triggers the creation of a shared Teleconsultation folder (TCF) for the specific episode. During the teleconsultation, collaborating healthcare professionals review the material in the shared TCF. Additional material may be added to the TCF folder on demand. Additional tools such as real-time vital signs monitoring and a digital stethoscope facilitate the construction of more accurate picture of the patient's state. The expert may enter a signed diagnostic report, which becomes part of the TCF. After the end of the telemedicine session, concluding reports are added, and the TCF is archived. At that point the TCF becomes part of the patient's I-EHR and authorized professionals may access its contents.

Each telemedicine service option uses a set of clinical document templates, which are submitted before or during a telemedicine session. Clinical document templates correspond to structured forms that are filled out by healthcare professionals in the context of a telemedicine session e.g. request for consultation, diagnostic report, progress note, etc. Clinical document templates validate against the "CDA Level One" specification [4]. They are comprised of a header, referred to as the "CDA Header" and a body, which at CDA Level One is referred to as the "CDA Level One Body." The CDA Header identifies and classifies the document and provides information on the document authenticator, the patient, the encounter, provider, and other service actors.

In general, each clinical document template consists of XML fragments, which are the units of reuse among document templates. Thus, XML fragments are used to assemble clinical document templates. XML fragments may be linked to middleware services of the HII for terminology, resources, profiles, security, and certification, to allow retrieval of up-to-date information. Additionally, XML fragments may be linked to EHR data sources using methods like OMG COAS (<http://www.omg.org>) and JDBC, to facilitate the automatic retrieval of objective medical data based on the suspected medical problem.

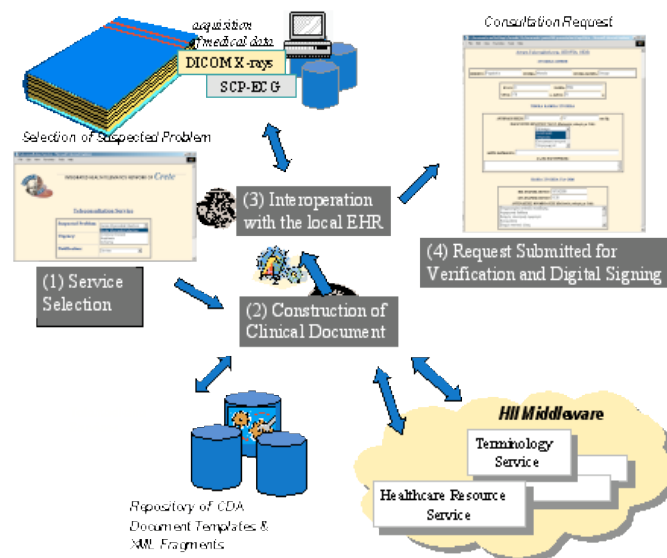


Figure 3: Process of creating a CDA document

Once the clinical documents reach their final form, the local markup is removed by applying an appropriate XSL style sheet. Multimedia documents such as ECGs or x-rays are linked into the clinical document. The author is authenticated, the clinical document is digitally signed, and both the clinical document and the digital signature are stored in the shared TCF. This process of creating a CDA document appears in **Figure 3**.

Deployment of a telemedicine service involves configuring the clinical document templates at the remote side to enable interoperability with local EHR systems and middleware services of the HII. Additionally, styles sheets for clinical documents are adapted to reflect the originating healthcare organization. Clinical document templates at the remote site are also configured to interface a number of medical devices such as a 12 lead digital Echocardiograph, and a 12-bit medical scanner for x-rays. Software components embedded in clinical document templates are responsible for searching or acquiring medical data and, if necessary, translate it into a standard format such as SCP for ECGs and DICOM 3.0 for images. These software components (typically ActiveX technology) are removed at the transformation of the clinical document template to the CDA document that will be included in the TCF.

Interregional Services

In the PICNIC project we have worked closely with other regions to harmonize our implementations of the CDA Level 1. This work was very important in view of the different applications and different health systems that were put on the table. The effort that was required for this task was largely underestimated. However, it allowed us to note the issues and took us a step further towards the deployment of interregional services.

5. CDA developments in FUNEN

During the specification phase of PICNIC the Collaboration IT-service was been identified.

The development will include 2 common components in Open Source:

1. The **Collaboration Server** provides the technological platform that will allows general practitioners and medical experts to share patient-related information in the context of a teleconsultation session both inside and across Regional Health Care Networks.
2. The **Resource Server** provides static information on the health care actors in the region (e.g. organizations, devices, software, etc.) and the means for accessing them. Examples of resources include healthcare professionals on-duty, hospitals and clinics, clinical information systems and services offered in the region, methods and technologies available for accessing primary information, and protocols for the exchange of information.

The components of the PICNIC collaboration IT service provide the necessary functionality for healthcare agents to browse dynamic availability and possibly cost information for various regional services. Once a service is selected and booked, in the context of a collaboration session further medical data (e.g. teleconsultation) as well as reimbursement data may be exchanged.

The exchange of structured data will be based on HL7-CDA Level 1. The 10 years experience in Denmark on datasets for exchange of structured data, will give an important input to the CDA documents. However there will be several decisions to make in order to refine the CDA for use in a specific setting. The discussions are among other: When to use national/regional coding sets instead of the US based coding sets, how to use national patient identifiers and other identifiers, and – since the CDA does not seem to be intended for request of service – how to handle the useful RECIEVER attribute.

The documentation of the Collaboration IT-service will include a set of guidelines to be used by the industry to make their application compliant with the service.

Regarding functionality, the collaboration IT service will keep on-line information about:

- Applications/users currently connected
- Type of health care specialists available
- Pricelist for different type of resources
- Profile for organisation and individual health care specialists
- Type of information which can be exchanged (images, video, sound, structured text, unstructured text, booking of resources, supported standards)
- Reimbursement.

Towards Seamless Interregional Collaboration Services in Health Care

It is important to agree on types of events, which can take part in collaboration. This will be implemented in an event description handler supporting different workflows for different type of “treatment”/diagnosing processes. The events are typically message information, which are exchanged between two applications (referral, image, video, clinical e-mail, x-ray report...).

Below is a typical workflow for a person who has been injured in a traffic accident. The person is unconscious and there are visible signs of head trauma. He has been admitted to the local hospital. The local Hospital has made a CT/MR examination but does not have the optimal professional skills and is asking for a second opinion on the CT/MR images.

The collaboration component supports the following scenario:

- Search for neurologist which are on-line and who can assist within the next 2 hours.
- Reply: A neurologist in the University Hospital is available in 30 minutes.
- A booking request is transferred. (HL7-CDA request)
- A booking reservation including prices is returned (HL7-CDA reservation)
- CT/MR images and a referral describing the patient’s clinical situation is transferred (DICOM images and (HL7-CDA referral)
- The neurologist examines the images and other information and returns a neurology/radiology report ((HL7-CDA report).

In PICNIC, the Collaboration IT-service will be demonstrated by setting up a real life Collaboration between sites in Denmark and Greece. The Collaboration common components will be used by the regional application.

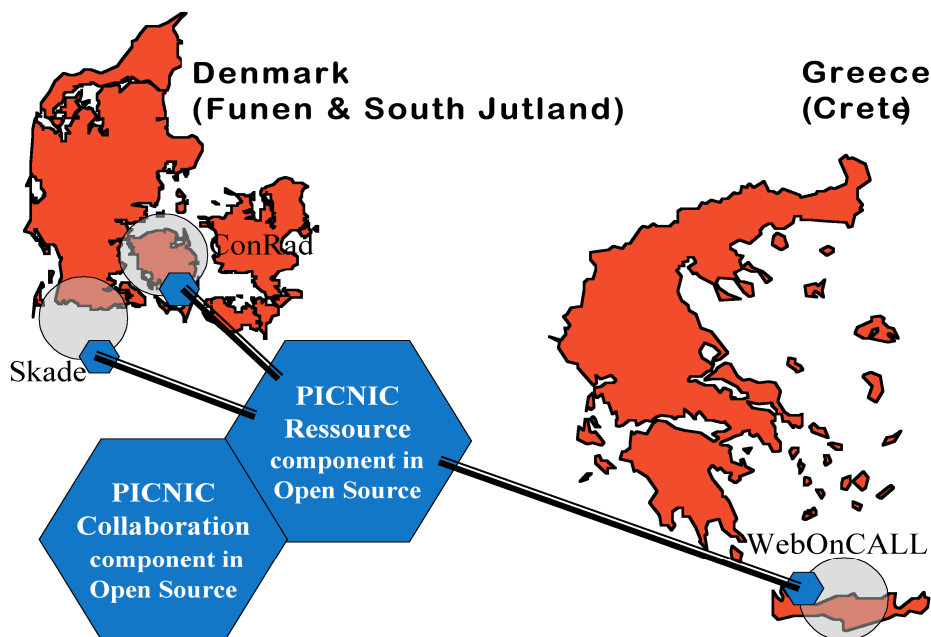


Figure 4. The Collaboration IT-service between Denmark and Greece

References

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3. Standard Communication Protocol for Computer-Assisted Electrocardiography, Version 1.0, CEN – Comité Européen de Normalisation, 1993
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7. 'D4.2 GMS Reimbursement Service Functional Specification, version 1.3',GMS(P)B, September 2000.
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9. 'D6.2 Messaging Common Components Harmonised Specification Version 3.0' May 2002, PICNIC.

APPENDIX 1: CDA HEADER DTD

```
<!-- ***** HEADER SPEC ***** -->

<!ELEMENT CLINICAL_DOCUMENT_HEADER (ID, Set_ID, Version_nbr?,
Document_type_cd, Origination_DTTM, Copy_DTTM?, Confidentiality_cd,
Fulfills_Order?, Patient_Encounter?, Authenticator?, Legal_Authenticator?,
Originating_Organization, Provider, Service_Actor?, Patient, Local_Header?)>

<!ELEMENT ID EMPTY>
<!ELEMENT Set_ID EMPTY>
<!ELEMENT Version_nbr EMPTY>
<!ELEMENT Document_type_cd EMPTY>
<!ELEMENT Origination_DTTM EMPTY>
<!ELEMENT Copy_DTTM EMPTY>
<!ELEMENT Confidentiality_cd EMPTY>

<!ELEMENT Fulfills_Order (Fulfills_Order.type_cd, Order)>
<!ELEMENT Fulfills_Order.type_cd EMPTY>
<!ELEMENT Order (ID)>

<!ELEMENT Patient_Encounter (ID)>

<!ELEMENT Authenticator (Authenticator.type_cd, Signature_cd)>
<!ELEMENT Authenticator.type_cd EMPTY>
<!ELEMENT Signature_cd EMPTY>

<!ELEMENT Legal_Authenticator (Legal_Authenticator.type_cd, Signature_cd)>
<!ELEMENT Legal_Authenticator.type_cd EMPTY>

<!ELEMENT Originating_Organization (Originating_Organization.type_cd,
Organization)>
<!ELEMENT Originating_Organization.type_cd EMPTY>
<!ELEMENT Organization (ID, Organization.nm)>
<!ELEMENT Organization.nm EMPTY>

<!ELEMENT Provider (Provider_type_cd, Person)>
<!ELEMENT Provider_type_cd EMPTY>
<!ELEMENT Person (ID)>

<!ELEMENT Service_Actor (Service_Actor.type_cd)>
<!ELEMENT Service_Actor.type_cd EMPTY>

<!ELEMENT Patient (Patient.type_cd, Person)>
<!ELEMENT Patient.type_cd EMPTY>

<!ELEMENT Local_Header (Local_attr+)>
```

<!ELEMENT Local_attr (#PCDATA)>

<!-- Headers attribute list-->

<!ATTLIST ID EX CDATA #REQUIRED>

<!ATTLIST Set_ID EX CDATA #REQUIRED>

<!ATTLIST Version_nbr V CDATA #REQUIRED>

<!ATTLIST Document_type_cd V (DP | GM | GR | LT | EU | HT | EM | HA | SO | DE | HD | ME | DC) #REQUIRED DN CDATA #REQUIRED>

<!ATTLIST Origination_DTTM V CDATA #REQUIRED>

<!ATTLIST Copy_DTTM V CDATA #REQUIRED>

<!ATTLIST Confidentiality_cd ID (CONF1 | CONF2 | CONF3 | CONF4) #REQUIRED V (S | T | I | N) #REQUIRED DN CDATA #REQUIRED>

<!ATTLIST Fulfills_Order.type_cd V CDATA #FIXED "FLFS">

<!ATTLIST Authenticator.type_cd V CDATA #FIXED "SPV">

<!ATTLIST Signature_cd V CDATA #REQUIRED>

<!ATTLIST Legal_Authenticator.type_cd V CDATA #FIXED "SPV">

<!ATTLIST Originating_Organization.type_cd V CDATA #FIXED "CST">

<!ATTLIST Organization.nm V CDATA #REQUIRED>

<!ATTLIST Provider_type_cd V CDATA #FIXED "CON">

<!ATTLIST Service_Actor.type_cd V CDATA #FIXED "GMS">

<!ATTLIST Patient.type_cd V CDATA #FIXED "PATSBJ">

<!ATTLIST Local_attr Name CDATA #REQUIRED Value CDATA #REQUIRED>

APPENDIX 2: EXAMPLE XML

```
<?xml version="1.0"?>
<!DOCTYPE CLINICAL_DOCUMENT_HEADER SYSTEM
"CdaHeaderNew.dtd">

<CLINICAL_DOCUMENT_HEADER>
  <ID EX="1234"/>
  <Set_ID EX="B"/>
  <Version_nbr V="1.2"/>
  <Document_type_cd V="DP" DN="Drugs Payment"/>
  <Origination_DTTM V="2001-12-07"/>
  <Copy_DTTM V="2001-12-07"/>
  <Confidentiality_cd ID="CONF3" V="I" DN="Individual access to persons who are
mentioned as actors"/>
  <Fulfills_Order>
    <Fulfills_Order.type_cd V="FLFS"/>
    <Order>
      <ID EX="56789"/>
    </Order>
  </Fulfills_Order>
  <Patient_Encounter>
    <ID EX="56548"/>
  </Patient_Encounter>
  <Authenticator>
    <Authenticator.type_cd V="SPV"/>
    <Signature_cd V="S"/>
  </Authenticator>
  <Legal_Authenticator>
    <Legal_Authenticator.type_cd V="SPV"/>
    <Signature_cd V="S"/>
  </Legal_Authenticator>
  <Originating_Organization>
    <Originating_Organization.type_cd V="CST"/>
    <Organization>
      <ID EX="565589"/>
      <Organization.nm V="James Street Pharmacy"/>
    </Organization>
  </Originating_Organization>
  <Provider>
    <Provider_type_cd V="CON"/>
    <Person>
      <ID EX="87956"/>
    </Person>
  </Provider>
  <Service_Actor>
    <Service_Actor.type_cd V="GMS"/>
  </Service_Actor>
  <Patient>
    <Patient.type_cd V="PATSBJ"/>
```

```
<Person>
  <ID EX="235689"/>
</Person>
</Patient>
<Local_Header>
  <Local_attr Name="Key1" Value="Value1"></Local_attr>
  <Local_attr Name="Key2"
Value="http://aaa.bbb.ccc?eka=1?toka=2"></Local_attr>
  <Local_attr Name="Key3" Value="Value3"/>
</Local_Header>
</CLINICAL_DOCUMENT_HEADER>
```