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Health informatics — Patient healthcard data —

Part 4: Extended clinical data

Informatique de santé — Données relatives aux cartes de santé des patients —

Partie 4: Données cliniques élargies

Reference number
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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 21549-4 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

ISO 21549 consists of the following parts, under the general title *Health informatics — Patient healthcard data*:

— *Part 1: General structure*

— *Part 2: Common objects*

— *Part 3: Limited clinical data*

— *Part 4: Extended clinical data*

— *Part 5: Identification data*

— *Part 6: Administrative Data*

— *Part 7: Electronic prescription (medication data)*

Introduction

With a more mobile population, greater healthcare delivery in the community and at patients' homes, together with a growing demand for improved quality of ambulatory care, portable information systems and stores have increasingly been developed and used. Such devices are used for tasks ranging from identification, through portable medical record files, to patient-transportable monitoring systems.

The functions of such devices are to carry and to transmit person-identifiable information between themselves and other systems; therefore, during their operational lifetime they may share information with many technologically different systems which differ greatly in their functions and capabilities.

Healthcare administration increasingly relies upon similar automated identification systems. For instance, prescriptions may be automated and data exchange carried out at a number of sites using patient transportable computer readable devices.

The advent of remotely accessible data bases and support systems has led to the development and use of "Healthcare Person" identification devices that are also able to perform security functions and transmit digital signatures to remote systems via networks.

With the growing use of data cards for practical everyday healthcare delivery, the need has arisen for a standardized data format for interchange.

The person-related data carried by a data card can be categorized in three broad types: i) identification (of the device itself and the individual to whom the data it caries relates), ii) administrative and iii) clinical. It is important to realize that a given healthcare data card "de facto" has to contain device data and identification data and may in addition contain administrative, clinical, medication and linkage data.

Device data is defined to include:

- identification of the device itself;
- identification of the functions and functioning capabilities of the device.

Identification data may include:

- unique identification of the device holder or of all other persons to whom the data carried by the device are related.

Administrative data may include:

- complementary person(s) related data;
- other data (distinguishable from clinical data) that are necessary for the purpose of healthcare delivery.

Clinical data may include:

- items that provide information about health and health events;
- their appraisal and labelling by a healthcare provider (HCP);
- related actions planned requested or performed.

Because a data card essentially provides specific answers to definite queries whilst having at the same time a need to optimize the use of memory by avoiding redundancies, “high level” Object Modelling Technique (OMT) has been applied with respect to the definition of healthcare data card data structures.

This part of ISO 21549 describes and defines the Extended Clinical Data objects used within or referenced by patient held health data cards using UML, plain text and Abstract Syntax Notation (ASN.1)[13].

This part of ISO 21549 does not describe and define the common objects defined in ISO 21549-2, even though they are referenced and utilized within this document.

Health informatics — Patient healthcard data —

Part 4:
Extended clinical data

1 Scope

This part of ISO 21549 is applicable to situations in which such data are recorded on or transported by patient healthcare data cards compliant with the physical dimensions of ID-1 cards defined by ISO 7810.

This part of ISO 21549 specifies the basic structure of the data contained within the data object extended clinical data, but does not specify or mandate particular data-sets for storage on devices.

In order to facilitate interoperability, whenever an application is built for use in the healthcare domain in compliance with ISO 21549, data items required for that application shall be drawn from the list of objects (some of which are extensible) as provided in Clauses 6 and 7. These shall then be used in conjunction with other data defined in other parts of ISO 21549.

The detailed functions and mechanisms of the following services are not within the scope of this part of ISO 21549, (although its structures can accommodate suitable data objects specified elsewhere):

- the encoding of free text data;
- security functions and related services, which are likely to be specified by users for data cards depending on their specific application, for example: confidentiality protection, data integrity protection, and authentication of persons and devices related to these functions;
- access control services, which may depend on active use of some data card classes such as microprocessor cards;
- the initialization and issuing process (which begins the operating lifetime of an individual data card, and by which the data card is prepared for the data to be subsequently communicated to it according to this part of ISO 21549).

The following topics are therefore beyond the scope of this part of ISO 21549:

- physical or logical solutions for the practical functioning of particular types of data cards;
- how the message is processed further “downstream” of the interface between two systems;
- the form which data takes for use outside the data card, or the way in which such data are visibly represented on the data card or elsewhere.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 7810:2003, *Identification cards — Physical characteristics*

ISO 21549-2:2004-05, *Health informatics — Patient healthcard data — Part 2: Common objects*

ISO 21549-3:2004-05, *Health informatics — Patient healthcard data — Part 3: Limited clinical data*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
clinical information
information about a subject of care, relevant to the health or treatment of that subject of care, which is recorded by or on behalf of a healthcare professional

NOTE 1 Clinical data/information are/is related to the health and healthcare of an individual, collected from or about an individual receiving healthcare services. It includes a caregiver's objective measurement or subjective evaluation of a patient's physical or mental state of health; descriptions of an individual's health history and family health history; diagnostic studies; decision rationale; descriptions of procedures performed; findings; therapeutic interventions; medication prescribed; description of responses to treatment; prognostic statements; and descriptions of socio-economic and environmental factors related to the patient's health. [ASTM E1769, CPRI]

NOTE 2 Clinical information about a subject of care may include information about the subject of care's environment or about related people where this is relevant.

[EN 14720-1]

3.2
data object
collection of data, which has a natural grouping and may be identified as a complete entity

3.3
healthcard holder
individual transporting a healthcare data card that contains a record with the individual identified as the major record person

3.4
healthcare data card
machine-readable card, conformant to ISO 7810, intended for use within the healthcare domain

3.5
healthcare party
organization or person involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE Healthcare parties are a subset of healthcare agents.

[EN 14720-1]

3.6
linkage
ability to join together two or more entities or parts

NOTE It may be physical, electrical or relational.

3.7
record
collection of data

3.8
record person
individual about whom there is an identifiable record containing person-related data

3.9
relaying agent
party agreed to be acting as an intermediary, communicating messages between the requesting and requested healthcare parties in both directions when direct communication is not possible as the requested healthcare party's identity is not known, being dependent on individual patient's choice

4 Symbols and abbreviated terms

ASN.1 Abstract Syntax Notation version 1

EN European Norm

HCP Healthcare person

HDC Healthcare data card

IEC International Electrotechnical Commission

ISO International Organization for Standardization

UML Unified Modelling Language

UTC Coordinated Universal Time

5 Basic data object model for a healthcare data card

5.1 Patient HDC data object structure

A set of basic data objects has been designed to facilitate the storage of clinical data in a flexible structure, allowing for future application specific enhancements. These tools should help the implementation of common accessory characteristics of stored data in a way that allows efficient use of memory, an important feature for many types of data cards.

The tools consist of a generic data structure based on an object-oriented model represented as a UML class diagram as shown below in Figure 1.

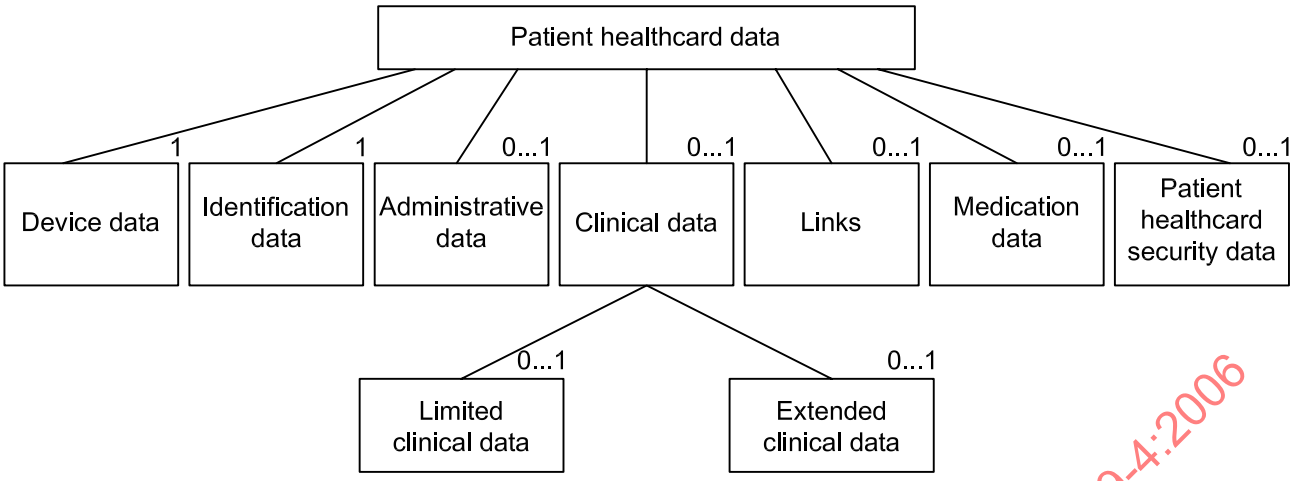

Figure 1 — Patient healthcard data — overall structure

The content of this object-oriented structure, described both below and intrinsically, will also require the use of data objects not defined within this part of ISO 21549.

NOTE It is possible to take the data objects and recombine them whilst preserving their context specific tags, and to define new objects, while still preserving interoperability.

In addition to the capability of building complex aggregate data objects from simpler building blocks, this part of ISO 21549 allows for associations between certain objects, so that information can be shared. This feature is mainly used to allow, for example, a set of accessory attributes to be used as services to several stored information objects.

5.2 Basic data objects for referencing

5.2.1 Overview

A series has been made of generally useful data type definitions that have no intrinsic value in themselves, but which are used to define other objects within this part of ISO 21549. Operations may be performed with these objects in association with other information objects to “add value”. These objects have formal definitions in ISO 21549-2.

5.2.2 Coded data

Coded values are understood by reference to the coding scheme to which they apply. The general principle in this part of ISO 21549 is that it is not mandatory to use a particular coding scheme, unless specified within this part of ISO 21549, when such codes act as parameters. One example is the use of ISO 3166-1 for country codes.

When a coding scheme is exclusively specified within this part of ISO 21549 no alternative coding scheme shall be allowed. Any references to coding schemes not so specified may, however, be modified in the future independent of the rest of this part of ISO 21549.

The data object “CodedData” shall be constructed according to the definition contained in ISO 21549-2.

5.2.3 Device and data security attributes

Data stored in data cards used in health care may be personally sensitive. For this reason this part of ISO 21549 utilises a series of security attributes, defined in ISO 21549-2. The actual data content (value) is not within the scope of this part of ISO 21549, nor are the mechanisms that make use of these data elements.

It is emphasised that the security attributes cannot satisfy given security requirements without the implementation of the appropriate security functions and mechanisms within the data card.

Such rights of “access” are attributable to specific individuals with respect to discrete data items. These rights will be defined by application developers and can be controlled by automated systems such as health care professional cards. The rights may be defined at the application level, thereby providing application and potential country specificity.

The “SecurityServices” data object provides for the storage of data required to deliver these security functions and mechanisms. This data can be “attached” to individual data elements, thereby preserving the original author's security requirements when the data object is transferred between different forms of data card. This mechanism may therefore ensure that in the process of transferring data from active to passive media and then back to active media, the original security requirements are re-generated. This ability also allows exact replication of a data card such as on regeneration after failure.

5.2.4 Accessory attributes

The data object “AccessoryAttributes” shall consist of an ordered set of data that are essential to record an audit trail regarding both the originator of the information and the means via which it arrives to the recipient as defined in ISO 21549-2.

6 Functional requirements on card information for extended clinical data

6.1 Overview of supported uses

The major consideration in this part of ISO 21549 is for HDC:

- to carry clinical messages (orders, referrals and reports) between the loosely coupled healthcare parties (i.e. parties that aren’t able to establish network connections or do not yet have third trusted party);
- to carry the links and access keys to clinical messages between the tightly coupled healthcare parties (i.e. parties that are able to establish network connection and have third trusted party);
- to carry coded summaries of diagnosis and procedures extending limited clinical data set described in ISO 21549-3. These summaries may be considered as the national or even institutional extensions of limited clinical data.

6.2 Clinical message transfer between healthcare parties

HDC designed to transfer clinical messages between healthcare parties shall be considered as a secure data media for a relaying agent. Such HDC may receive clinical messages without a predefined target healthcare party and may also play a role in authenticating the eligibility of the healthcare party to retrieve these clinical data.

7 Extended Clinical Data

7.1 General

The Extended Clinical Data object is specifically divided into three separate data objects, index of clinical events (class *ClinicalEventDescription*), sequence of mapped clinical messages (class *MappedClinicalMessage*) and extended emergency data (class *ExtendedEmergencyData*). Because of their groupings, each of these can have differing security settings, including access rights as determined by the provisions contained within accessory attributes (class *AccessoryAttributes*).

See Figure 2 and Table 1.

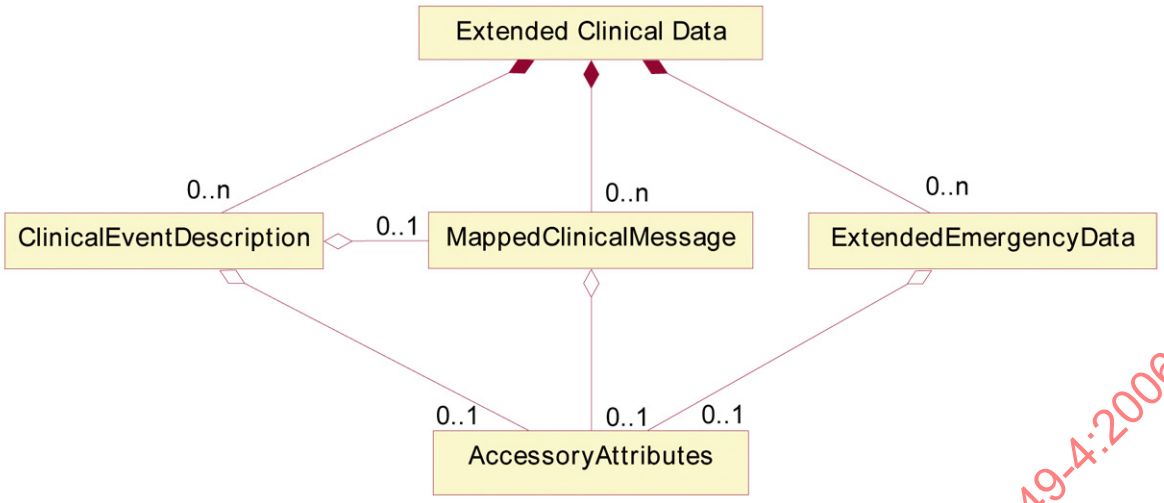

Figure 2 — The structure of Extended Clinical Data set

Table 1 — The specification of individual entities within Extended Clinical Data set

Object name	Object type	Multiplicity	Comments
ClinicalEventDescription	Class	0..n	This class holds the description of a clinical event registered on to HDC
MappedClinicalMessage	Class	0..n	This class holds a mapped clinical message carrying information of registered clinical event
ExtendedEmergencyData	Class	0..n	This class holds coded extended emergency data

7.2 The Clinical Event Description

An object “ClinicalEventDescription” shall consist of a set of data consisting of a clinical event identifier, a type and a subtype (control code) of this event and also date, time and place of event. This object may contain the optional element “AccessoryAttributes”. This object is intended to support the process of a selection of the relevant clinical message.

According to Figure 3, an instance of Clinical Event Description may reference an instance of the mapped clinical message and an instance of accessory attributes. See also Table 2.

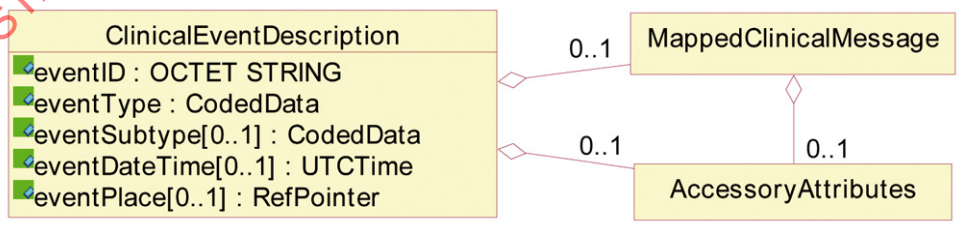

Figure 3 — Structure of Clinical Event Description data set

Table 2 — The specification of individual entities within Clinical Event Description data set

Attribute name	Data TYPE	Multiplicity	Comments
eventID	OCTET STRING	1	This identifies a clinical event in a manner allowing the originator of the related clinical message to identify this event uniquely
eventType	CodedData	1	This identifies type of the clinical event (order, referral, discharge, result of clinical investigation and so on)
eventSubtype	CodedData	0..1	This identifies subtype of the clinical event needed for control (new order, cancel order and so on)
eventDateTtime	UTCTime	0..1	This identifies date and time of clinical event
eventPlace	RefPointer	0..1	This references identifier of a location or a system where the clinical event took place or was registered
clinMessPointer	RefPointer	0..1	This references the mapped clinical message
accessoryAttributesPointer	RefPointer	0..1	This references the accessory attributes

7.3 The Mapped Clinical Message

An object “MappedClinicalMessage” shall carry information on the clinical event. This information contains in the clinical message triggered by this event and directed by a service requester to a service provider or vice versa.

According to Figure 4, each instance of Mapped Clinical Message shall be referenced by one instance of Clinical Event Description. See also Table 3.

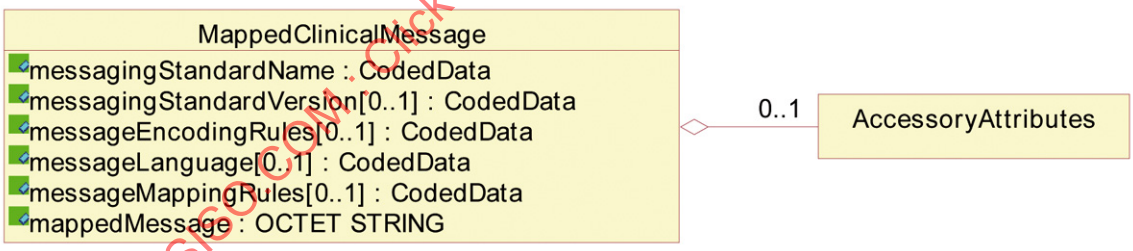

Figure 4 — Structure of Mapped Clinical Message data set

Table 3 — The specification of individual entities within Mapped Clinical Message

Attribute name	Data type	Multiplicity	Comments
messagingStandardName	CodedData	1	This identifies messaging standard used by the originator of the message
messagingStandardVersion	CodedData	0..1	This identifies messaging standard used by the originator of the message
messageEncodingRules	CodedData	0..1	This identifies messaging encoding rules used by the originator of the message
messageLanguage	CodedData	0..1	This identifies principal language of message
messageMappingRules	CodedData	0..1	This identifies mapping rules used by a card application while writing the message into HDC
mappedMessage	OCTET STRING	1	This is the mapped message itself
accessoryAttributesPointer	RefPointer	0..1	This references the accessory attributes

7.4 The Extended Emergency Data

An object “ExtendedEmergencyData” shall carry information supplemental to the Limited Clinical Data defined in ISO 21549-3. This information contains coded clinical data.

See Figure 5 and Table 4.

Figure 5 — Structure of Extended Emergency Data set

Table 4 — The specification of individual entities within Extended Emergency Data

Attribute name	Data type	Multiplicity	Comments
emergencyItem	ConceptDescriptor	1	This is a coded descriptor of procedure, patient problem or diagnosis
onsetDateTime	UTCTime	0..1	This is date and time of procedure, patient problem or diagnose

Annex A
(normative)

ASN.1 Data definitions

```
ClinicalEventDescription    ::= SET
{
        eventID                         [0] OCTET STRING,
        eventType                       [1] CodedData,
        eventSubtype                    [2] CodedData    OPTIONAL,
        eventDateTime                   [3] UTCTime      OPTIONAL,
        eventPlace                      [4] RefPointer   OPTIONAL,
-- This is a pointer to a person/place identifier stored elsewhere
        clinMessPointer                 [5] RefPointer   OPTIONAL,
-- This is a pointer to a clinical message stored elsewhere
        accessoryAttributesPointer      [6] RefPointer   OPTIONAL
-- This is a pointer to the accessory attributes stored elsewhere
}
MappedClinicalMessage    ::= SET
{
        messagingStandardName           [0] CodedData,
        messagingStandardVersion        [1] CodedData    OPTIONAL,
        messageEncodingRules            [2] CodedData    OPTIONAL,
        messageLanguage                 [3] CodedData    OPTIONAL,
        messageMappingRules             [4] CodedData    OPTIONAL,
        mappedMessage                   [5] OCTET STRING,
        accessoryAttributesPointer      [6] RefPointer   OPTIONAL
}
```

```
ExtendedEmergencyData  ::= SET
{
      emergencyItem                [0] ConceptDescriptor,
      onsetDateTime                [1] UTCTime,
      accessoryAttributesPointer   [2] RefPointer      OPTIONAL
-- This is a pointer to the accessory attributes stored elsewhere
}
ConceptDescriptor ::= SET
{
      conceptCode                  [0] OCTET STRING,
      conceptName                  [1] OCTET STRING  OPTIONAL,
      codingSchemePointer          [2] RefPointer,
-- This is a pointer to the coding scheme stored elsewhere
      conceptOriginalText          [3] OCTET STRING  OPTIONAL,
      conceptTranslation           [4] SET OF ConceptDescriptor,
      conceptQualifier             [5] SEQUENCE OF QualifierRole
}

QualifierRole ::= SET
{
      qualifierName                [0] CodedData,
      qualifierValue               [1] ConceptDescriptor,
      qualifierInverted            [2] BOOLEAN
}
```

Annex B
(informative)

Rationale of extended clinical data structure

B.1 Introduction

The request for clinical order or referral is usually accompanied by a relevant subset of the clinical information held by the requesting healthcare professional about the patient – subject of the order or referral. The recipient of the order or the referral usually reports on the progress and outcome of the requested service. These reports may be made when the requested service is completed or at other significant points in the delivery of the requested service. The information that is transferred in the requests and reports passing between healthcare professionals typically forms part of the administrative and clinical record of the patient held by each of the communicating parties. Electronic transfer of these requests and reports reduces the need for manual data entry and the risk of transcription errors. It also results in greater efficiency leading to better healthcare provision.

HDC may facilitate the electronic transfer of the orders, referrals and reports by several ways. First of all, they may carry the orders, referrals and reports between the loosely coupled healthcare parties (i.e. parties that are not able to establish network connections or do not have third trusted party yet). HDC may also carry the links and access keys to the relevant subsets of the electronic patient's record between the tightly coupled healthcare parties (i.e. parties that are able to establish network connection and have third trusted party).

HDC coupled with the appropriate card application (card system) may be considered as a relaying agent in terms of ENV 13607[1]. See Figure B.1.

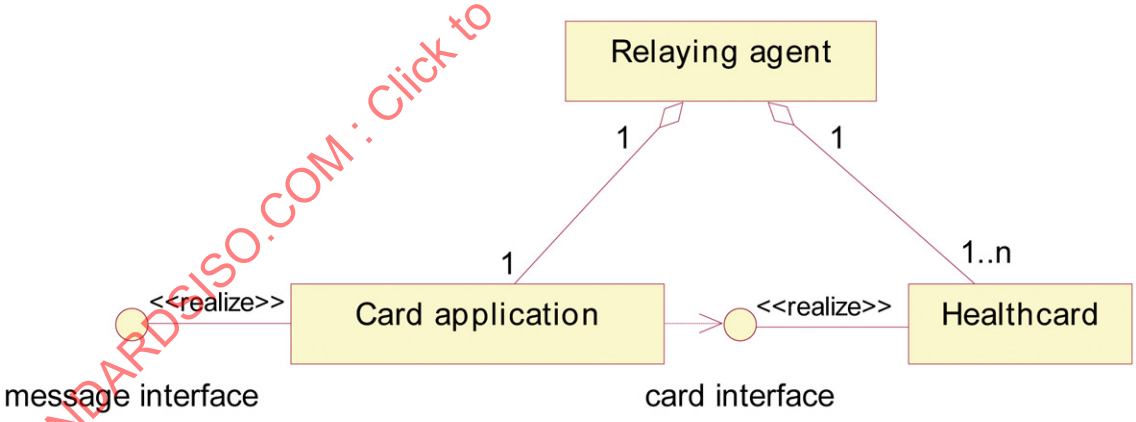

Figure B.1 — HDC as a component of relaying agent

In case of clinical orders and referrals, the relaying agent is a party agreed to be acting as an intermediary, communicating messages between the requesting and requested healthcare parties in both directions when direct communication is not possible as the requested healthcare party's identity is not known, being dependent on individual patient's choice (Figure B.2). Such a relaying agent is also entrusted with the role of receiving new order or referral from the requesting party without a predefined requested party. The relaying agent may also play a role in authenticating the eligibility of the requested party to retrieve extended clinical data.

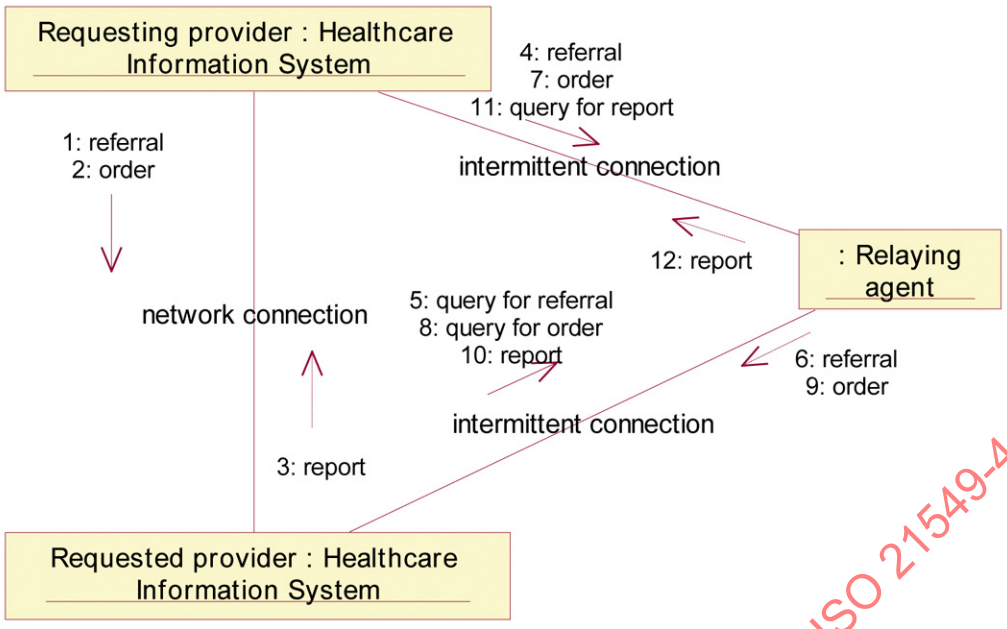

Figure B.2 — Relaying agent as intermediary between requesting and requested providers

In order to play a role of orders, referrals and reports storage for relaying agent, HDC is to be able to carry extended clinical data in addition to emergency data set, medication data, identification and administrative data. Standards are required to define structure of extended clinical data carried by HDC between the many systems currently used. Implementation of these standards facilitates electronic exchange of orders, referrals and reports between both loosely and tightly coupled healthcare parties, reduces the need for manual entry and the risk of transcription errors. It also results in greater efficiency leading to better healthcare provision.

B.2 Extended clinical data structure construction

Extended clinical data objects that are proposed in this part of ISO 21549 are derived from definitions of relevant data objects given by existing standards of electronic orders/referrals/reports exchange including but not limited to:

— EN 14720-1[2]

— HL7 Version 2 Chapter 4 Order Entry, Chapter 7 Observation Reporting, Chapter 11 Patient Referral

— HL7 Clinical Document Architecture

— UN/EDIFACT Messages MEDREQ and MEDRPT

— DICOM 3.0

This approach implies that the relevant parts of the messages defined in these standards are to be mapped to and from proposed extended clinical data structure. Such a mapping may be performed by an intermediate card application (Figure B.1). It may be done at different levels of the message structure: message level, message parts level, message elements level (Figure B.3).

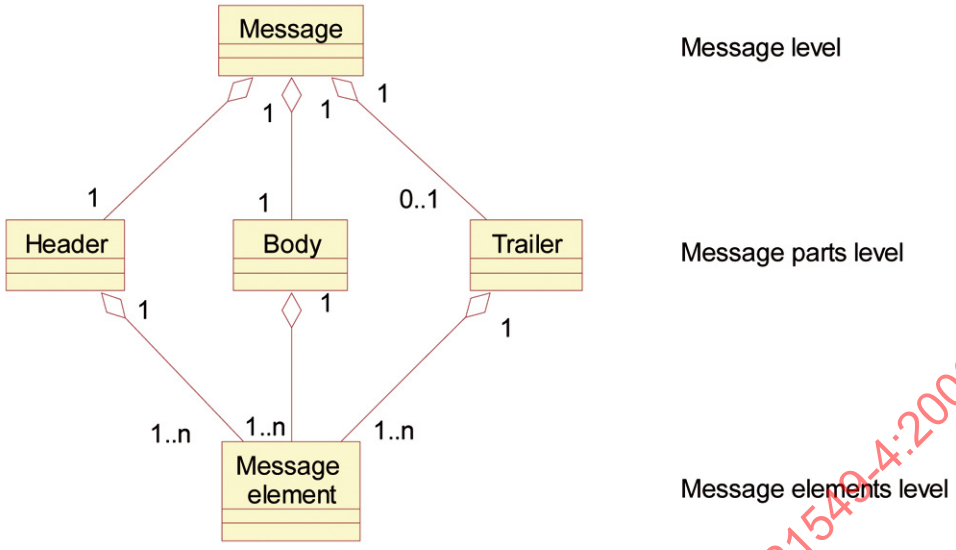

Figure B.3 — The levels of the message structure

ASC X12N faced a similar problem, that of constructing the clinical data structure for healthcare claims attachment, several years ago. This committee has adopted mapping of HL7 Version 2 clinical order messages on the first message level: the whole ORU (Observational Report Unsolicited) message is embedded in binary segment BIN. This approach significantly simplifies the task of the implementation and maintenance of the standard.

If HDC memory is small then HDC may not be able to carry the mapped clinical messages. The new HDC may have memory up to several hundred MByte. So this disadvantage is not crucial.

HDC should contain not only embedded clinical messages but also some kind of supporting data structure. This structure may be derived from collaboration diagrams shown in figure B.4.

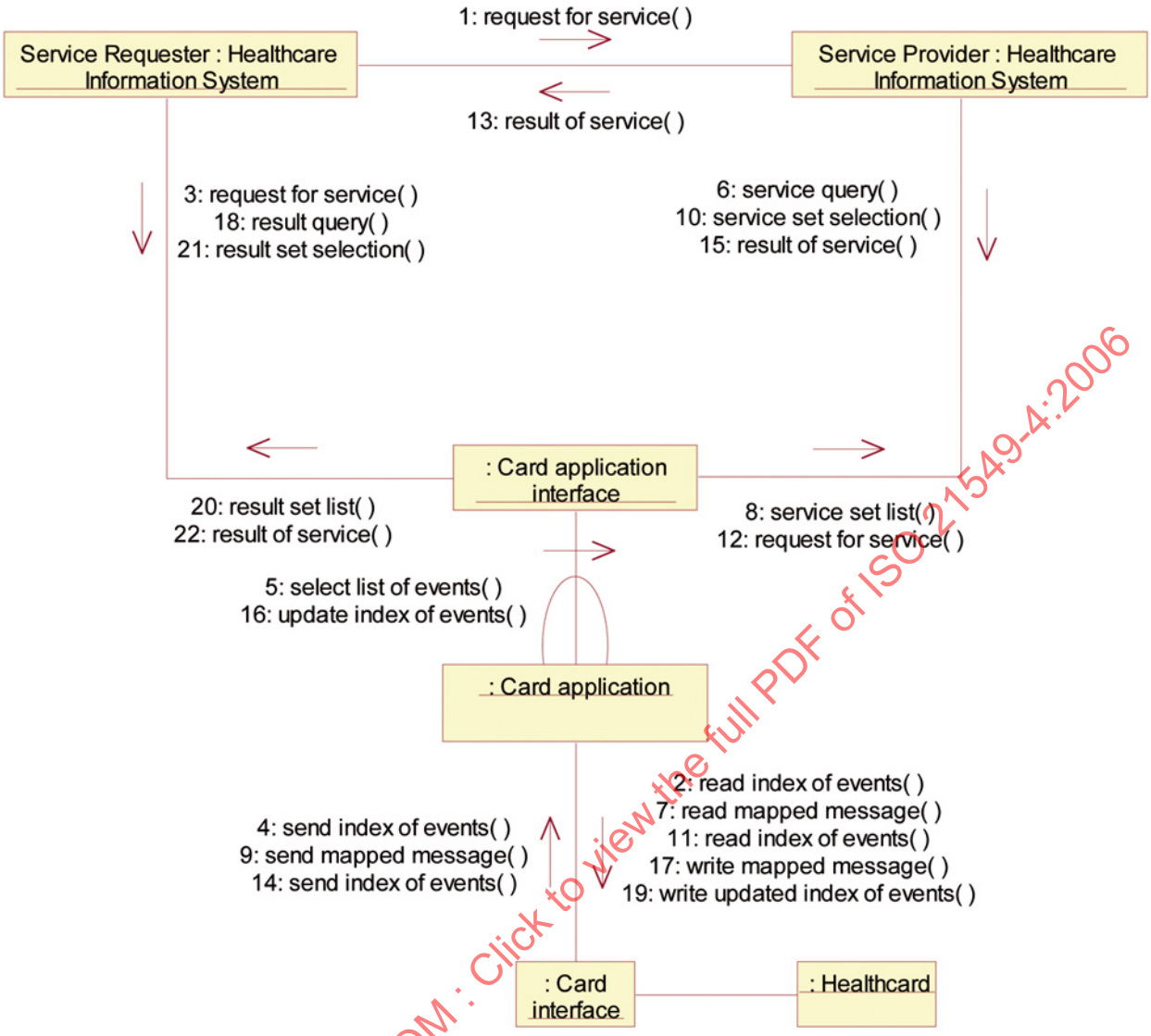

Figure B.4 — Interactions between health information systems and HDCs carrying clinical messages

A service requester may send request for service (order or referral) directly to a service provider or may forward it to an HDC through a card application interface. When a patient – the HDC holder – visits the service provider he or she grants rights of HDC usage to this provider. HDC may carry many requests for service so the service provider shall first of all query the relevant requests and then select a proper request from the returned list. A similar procedure should be undertaken by the service requester to receive information on the result of the requested service. So the card application reads an index of the related clinical events from HDC or builds this index by polling the embedded clinical messages. The latter method is not suitable because HDC may carry a huge volume of clinical data and message polling may become very time-consuming; so HDC shall contain both embedded clinical messages and index of clinical events related to these messages. If memory capacity of HDC does not allow carrying of the clinical messages then this card may contain only the index of events. The knowledge of the fact of the event may be useful even in the absence of the related message in the card memory. Having event ID, the healthcare party may query message originator for detailed clinical information using network connection or simply by telephone.

HDC may also carry the coded summary of the patient problems, diagnosis or procedures. Such a summary extends the limited clinical data set defined in ISO 21549-3. It may be useful in an emergency. Each entry of this summary contains coded phrase constructed from the relevant clinical classification or coding system, for example ICD, CPT, SNOMED International, SNOMED RT, SNOMED CT. The definition of the type ConceptDescriptor is derived from the definition of data type CD to be defined in ISO 21090.