

Medical informatics — Healthcare Information System Architecture (HISA) —

Part 1: Healthcare Middleware Layer

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National foreword

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This publication is not to be regarded as a British Standard.

It is being issued in the Draft for Development series of publications and is of a provisional nature due to the limited duration of the European prestandard. It should be applied on this provisional basis, so that information and experience of its practical application may be obtained.

Comments arising from the use of this Draft for Development are requested so that UK experience can be reported to the European organization responsible for its conversion into a European Standard. A review of this publication will be initiated 2 years after its publication by the European organization so that a decision can be taken on its status at the end of its three-year life. The commencement of the review period will be notified by an announcement in *Update Standards*.

According to the replies received by the end of the review period, the responsible BSI Committee will decide whether to support the conversion into a European Standard, to extend the life of the prestandard or to withdraw it. Comments should be sent in writing to the Secretary of BSI Technical Committee IST/35, Medical informatics, at 389 Chiswick High Road, London W4 4AL, giving the document reference and clause number and proposing, where possible, an appropriate revision of the text.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the ENV title page, pages 2 to 79 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

This Draft for Development, having been prepared under the direction of the DISC Board, was published under the authority of the Standards Committee and comes into effect on 15 November 1998

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Amendments issued since publication

Amd. No.	Date	Comments

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English version

Medical Informatics — Healthcare Information System Architecture (HISA) — Part 1: Healthcare Middleware Layer

This European Prestandard (ENV) was approved by CEN on 5 January 1998 as a prospective standard for provisional application.

The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into a European Standard.

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 251 “*Medical informatics*”, the secretariat of which is held by SIS.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Annex A, Annex B, Annex C, Annex D, Annex E and Annex F are informative.

Non-technical readers are advised to start analysis of the document with Annex C which provides an introduction to the objectives of the architecture and the technical background underlying its specification.

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Introduction

Healthcare organisational structure in all European countries consists of networks of centres distributed over the territory, characterised by a high degree of heterogeneity and diversity, from organisational, logistic, clinical and even cultural perspectives. The structure of individual centres is evolving from a vertical, aggregated organisation towards the integration of a set of specialised functional areas, with specific needs and characteristics. Such a situation determines two main needs which conflict with each other in a certain way. On the one hand it is necessary to support effectively the specific requirements of each unit or user in the most appropriate and cost-effective way whilst on the other hand it is vital to ensure the consistency and integration of the overall organisation, both at local and territorial level.

The large number of applications, mutually isolated and incompatible, that are already available on the market and installed and operational in healthcare organisations, effectively supporting specific needs of users cannot be underestimated. Under the present circumstances, the main need is to make possible the integration and interoperability of already existing applications thereby securing investments already made and allowing continuity of the service whilst facilitating a gradual migration of existing proprietary, monolithic systems towards the new concepts of openness and modularity. The cost-effectiveness of the solutions, especially when projected on the scale of the whole organisation, represents another crucial aspect to be evaluated carefully.

Such objectives are not only related to the need for improving clinical treatments to the subject of care but are also demanded by the urgent necessity of all European countries to control and optimise the current level of expenditure for health, whilst ensuring the necessary qualitative level of services to all subjects of care. The purpose of the standard architecture is to identify a set of common services used within healthcare information systems, supporting specific requirements of the target organisation, as well as being capable of co-operating and interworking according to the requirements of the organisation as a whole.

The architecture is intended as a basis both for the comparison, evolution and integration of existing systems as well as for the planning and high-level design of new open and modular systems, capable of providing consistent and integrated support to the clinical, organisational and managerial requirements of healthcare organisations.

The standard architecture aims at presenting a practical tool, usable by different types of users, involved with different responsibilities during the whole life-cycle of the information system:

Suppliers

who plan and design high-level consistent information systems, meeting the actual requirements of healthcare organisations and capable of interworking in a generic information systems:

Consumers at managerial level

- to plan the implementation and evolution of the Healthcare Information System at strategic level according to organisational goals and requirements;
- to validate the compliance of different solutions with respect to the needs of the organisation;
- to facilitate the selection of different but integratable products;

Consumers at operational level

- to provide an active contribution to the technicians in the specification of the requirements for the system;
- to assess the basic compliance of individual solutions with their specific requirements.

General aims

- to provide a comprehensive and consistent, even if preliminary, framework for the integration of the two main foci of development, research and standardisation activities: patient treatment and management of the organisation;
- to define the scope of a set of subsequent fundamental standards, each capable of detailing the various components of the architecture to a level permitting the physical connection of different products in an open environment.

It should be stressed that this European Prestandard does not aim to recognise a unique model for clinical, organisational, managerial or administrative activities, but rather defines a set of healthcare-specific information and services common to all healthcare information systems, usable by any application, to manage mutual interworking.

This European Prestandard is a foundation standard and may require further standards as indicated in Annex C. In particular, further future standards detailing the aspects related to the description, formalisation and composition of the services should extend the specifications of this standard. These future standards should increase the level of accuracy and compliability suitable for the formalisation of the mechanisms according to which different software products may interact in a generic physical environment.

1 Scope

This European Prestandard establishes general principles for the architecture of healthcare information systems as well as the scope of a set of Healthcare Common Services, provided by the middleware layer of the healthcare information system. These services are fundamental in any generic information system for supporting the requirements of the management of the information related to the treatment of the subject of care.

This European Prestandard is independent of any specific technological environment and does not imply, either directly or indirectly, the adoption of any specific organisational, design or implementation solution.

This European Prestandard is applicable to the information systems of any type of healthcare organisation.

The specification of the characteristics of the identified Healthcare Common Services is limited to the sole formalisation of their external behaviour, in terms of their function and of the information to be made available to the rest of the system. Such behaviour is defined at the conceptual level only, through formalisms and notations suitable to identify the scope of the services.

This European Prestandard is limited to the identification of a set of common services capable of supporting that part of the information system related to the treatment of the subjects of care. The support for requirements specific to the management and administration of the healthcare infrastructure is not explicitly addressed by this European Prestandard. Due to the intrinsic integration of the organisation, services and information provided by the Healthcare Common Services identified, this European Prestandard does not explicitly exclude administrative and managerial requirements.

This European Prestandard does not specify the characteristic of any application or sub-system and, in particular, a healthcare record system of the healthcare information system. The services defined in this European Prestandard are used by the information system, including healthcare record systems, for the management of elementary information, relevant and common to the whole healthcare organisation.

This European Prestandard does not specify all possible classes of information and services which are necessary or useful in all possible healthcare information systems, but only as a fundamental set which is considered to be of major relevance. The set of services and information classes identified in this European Prestandard is not exhaustive. It may be extended in individual installations, according to specific requirements, depending on the particular nature of the information system, as well as on national and local needs.

2 Normative references

This European Prestandard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to, or revisions of any of these publications apply to this European Prestandard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies.

ISO 1087:1990, *Vocabulary of terminology*.

ISO/IEC 7498-1:1994, *Information technology — Open Systems Interconnection — Basic Reference Model: The Basic Model*.

ISO 10241:1992, *International terminology standards — preparation and layout*.

ENV 12017:1995, *Medical Informatics — Medical Informatics Vocabulary*.

prENV 12265:1996, *Medical Informatics — Electronic Healthcare Record Architecture*.

prENV 12443:1996, *Medical Informatics — Healthcare Information Framework*.

3 Definitions

For the purpose of this European Prestandard, the following definitions apply:

3.1

concept

unit of thought constituted through abstraction on the basis of properties common to a set of objects [ISO 1087]

3.2

data concept

entity or relationship defined within the structural view of the Healthcare Common Services

3.3

healthcare actor

person entrusted with the direct or indirect provision of healthcare services

3.4

healthcare information system architecture

structure of, and interrelationships with as well as relationship to the organisation and business context to be supported

3.5

Healthcare Common Services (HCS)

group of services provided by the healthcare middleware layer of the architecture to support the rest of the system with functions relating to the management of functionalities and of information common to the whole healthcare organisation and peculiar to the healthcare business domain

3.6

object

part of the perceivable or conceivable universe [ISO 1087]

3.7

property

attribute of a phenomenon, body or substance that may be distinguished qualitatively [ENV 1614]

3.8

software module

self-consistent set of computer executable programs, identifiable through a non-ambiguous criterion defined by its creator or user

3.9

service

function provided by one layer of the healthcare information system

NOTE Each service may be invoked by any module of the information system through a formal mechanism, to be documented in the specific installation according to a formal and unambiguous syntax, depending on the programming languages and technological environment adopted.

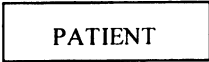
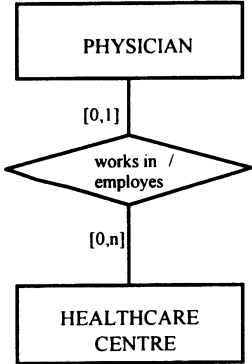
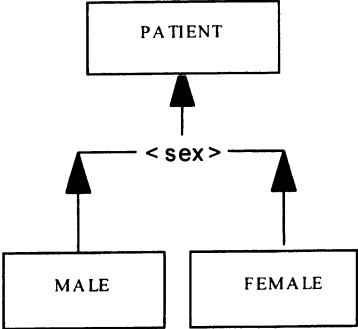
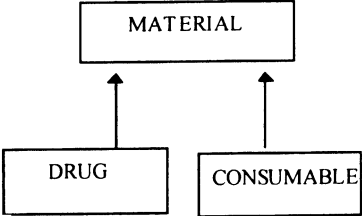
4 Symbols and abbreviations

The structure of the data exchanged by each Healthcare Common Service is described at the conceptual level, through the use of the following information object meta-types:

- entity;
- relationship;
- hierarchy;
- subset;
- attribute.

These information object meta-types are defined below, together with their respective graphical notations where applicable.

For the purpose of this European Prestandard, references to entities are in capitals. To improve readability in the text, entity names are sometimes shown in plural form.

ENTITY autonomous and self-consistent object of the domain of interest, with a set of common properties called attributes NOTE Graphically, an entity is represented by a rectangle.	
RELATIONSHIP fact that connects two entities NOTE 1 Graphically, a relationship is represented by a diamond, connected to the involved entities. NOTE 2 A relationship is bi-directional; it defines a mutual link between the connected concepts. The diamond contains two names, specifying the meaning of the relationship with respect to each entity. NOTE 3 A relationship has a cardinality with respect to each connected entity, which specifies the minimum and maximum number of occurrences of that relationship which may be related to any generic instance of the entity. NOTE 4 Cardinalities are shown close to the relationship and beside the line connecting the entity with the relationship. NOTE 5 Relationships may have specific properties, which relate to the fact itself and do not depend on the entities which are connected through the relationship. These properties are called <i>attributes</i>.	
HIERARCHY classifies one entity, by introducing a partition based on one set of discriminating attributes NOTE Graphically, the classification hierarchy is described through a set of arrows linking all sub-entities to the originating entity. The discriminating attribute is written on the line connecting all sub-entities. NOTE Each instance of the entity belongs to one and only one sub-entity. EXAMPLE: Classification of the patient is made through the <i>sex</i> attribute: a patient is either in the male or in the female sub-entity.	
SUBSET creates a classification in one entity, by identifying a group of instances with common properties, but without determining a partition in the entity. NOTE Graphically, a subset is represented with an arrow directly connecting the sub-entity with the entity. EXAMPLE: Two subsets, DRUG and CONSUMABLE, represent two groups in the whole entity of MATERIAL. A consumable material may also be a drug.	

5 Structure of a healthcare information system architecture

The architecture of any generic healthcare information system shall be described through three co-operative layers [prENV 12443]:

— Healthcare Application layer

models the data flows and functionalities required to support healthcare processes

There are applications consisting of application processes which perform information processing. An aspect of these application processes and the protocols by which they communicate comprise the healthcare application layer as the highest layer of the ISO/OSI architecture [ISO/IEC 7498-1];

— Healthcare Middleware layer

models shared services required to support the application layer.

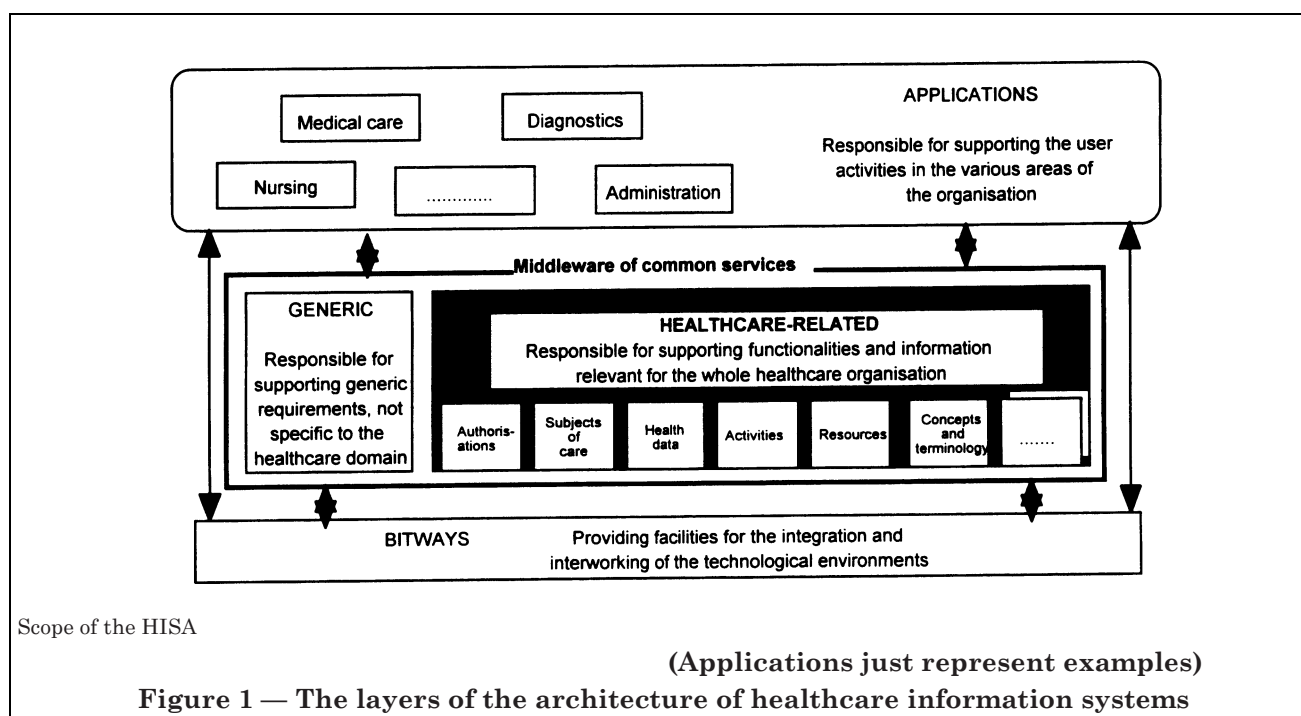
NOTE 1 Healthcare middleware layer is also known as basic services or enabling services.

NOTE 2 It consists of a group of services which provide the rest of the system with services common throughout the whole information system.;

— Healthcare Bitways layer

models technological infrastructure which provides services to the middleware layer.

NOTE 1 Healthcare bitways layer is also known as networking or physical infrastructure.



Two classes of services shall be identified in the middleware layer of any healthcare information system:

- **Healthcare Common Services** which support the applications with services relating to the management of functionalities and of information common to the whole healthcare information system and peculiar to the healthcare business domain;
- **Generic Common Services** which support the applications with general purpose facilities which are usually common to any information system in any type of business domain.

The scope of this European Prestandard, with respect to the three layers of the architecture, is limited as follows:

— Application layer

due to the variety of different healthcare organisations and the dependency of applications on specific local requirements no normative provision is made with respect to the characteristics and scope of individual applications;

— **Middleware layer**

identifies a fundamental set of Healthcare Common Services and formalises their scope and objectives with respect to the overall system, as well as the modalities for their interaction with the rest of the system, both in terms of functionalities provided and of information managed.;

— **Bitways layer**

due to the general applicability of such services in any information system, their specification is outside the scope of this standard.

The scope of this European Prestandard is limited, with respect to the level of specification, as follows:

— The characteristics of the individual services are expressed only in terms of their external behaviour, i.e. functionalities provided and information exchanged, without making, either implicitly or explicitly, any assumption on the actual design or implementation solution.

— The data model presented in the specification of each group of common services only has the purpose of formalising the characteristics of the information, i.e. concepts, attributes and relationships, which are exchanged with the rest of the system. Such models, therefore, do not aim at representing, either explicitly or implicitly, fragments of any possible physical data structure implemented in the system.

— According to the foundation purposes of this European Prestandard, the functionalities of the services are defined only through natural language, adopting terms which are used and familiar in the common practice of information technology. Such a level of formality allows the identification of the scope of the individual services.

The detailed specification of the interaction mechanisms of individual services, up to the level of allowing different software products to interact in a generic physical environment, is outside the scope of this European Prestandard.

— The services identified by this European Prestandard, as well as their individual characteristics, represent an open set of common properties fundamental for any type of healthcare information system.

NOTE Both the list of Healthcare Common Services and the properties, i.e. services and data, of each of them may be extended in the actual implementation according to local requirements as well as to subsequent national and international standards complementing this one.

In order to ensure the modularity and openness of the architecture, this European Prestandard does not define any normative provision with respect to possible interactions between individual services.

6 Rationale for the identification of the Healthcare Common Services

The purpose of the Healthcare Common Services provided by the healthcare middleware layer shall provide all parts of the healthcare information system with common functionalities to manage those functionalities and information which are common to the whole healthcare information system.

At a high level of abstraction- the essence of any healthcare environment can be described by the following paradigm:

In any healthcare organisation, different types of actors perform activities, using resources, and generating results.

Activities may be either directly or indirectly related to the needs of subjects of care or to general requirements of the organisation.

Depending on the type of activity which is being executed, the results of one activity may represent health characteristics of the subject of care, or simply, other data to be communicated through the healthcare organisation.

When executing one activity, a certain quantity of several resources is also used, such as staff members, consumable materials, physical agents and equipment. The utilisation of each resource has its specific cost, depending on the specific resource involved and on the type of activity performed.

Different types of users are authorised to work with the healthcare information system, and are allowed to perform activities or access various types of information, according to defined criteria, according to national and regional regulations, as well as local rules and the characteristics of the individual activities and data.

Several types of dependencies and relationships may exist among the types of concepts managed by the healthcare information system, relating to both the clinical and organisational aspects

In the healthcare domain view [prENV 12443] it is possible to aggregate logically classes of common information into six main groups, identifying for each of them a set of common services, each set referred to as HCS in the following text, responsible for the management of the related concepts:

- Subjects of Care Healthcare Common Services (S-HCS);
- Health Characteristic Healthcare Common Services (HC-HCS);
- Activity Healthcare Common Services (A-HCS);
- Resource Healthcare Common Services (R-HCS);
- Authorisation Healthcare Common Services (AU-HCS);
- Concept Healthcare Common Services (C-HCS).

The clustering of the classes of information managed by the healthcare middleware layer and of the related services into the six groups of Healthcare Common Services (HCS) specified in this European Prestandard represents just one possible way of structuring them according to a rationale depending on their main semantic aspects.

For the purpose of conformance to this European Prestandard, the healthcare middleware layer shall provide the healthcare information system with services and information as specified. Different implementations can group the individual information and services of the healthcare middleware layer on the basis of different rationales.

In the following clauses, the external behaviour of each group of Healthcare Common Services (HCS) is formalised. The specification of each group of Healthcare Common Services is structured in three parts:

- **scope**, outlining, in textual form, the main purpose of the services of that group of Healthcare Common Services within the framework of the healthcare information system;
- **structural view**, defining, at conceptual level, the fundamental classes of information which shall be managed by the services of that group of Healthcare Common Services;
- **functional view**, defining the fundamental functionalities which shall be provided by the services of that group of Healthcare Common Services to the rest of the healthcare information system.

NOTE 1 In the specification of the structural view of each HCS, the following conventions have been adopted:

- For each HCS the structural view consists of two sections: a graphic diagram representing the conceptual schema of the information managed, retrieved and referenced by the HCS and a set of textual descriptions, specifying the characteristics of the individual entities defined in the schema.
- Entities represented through shadowed symbols in a graphic schema are classified in the scope of a different HCS, and therefore specified only in the relevant textual section.
- The textual specification of each entity consists of the following sections:
 - Definition of the semantic meaning of the entity
 - Identification and definition of the sub-entities and of the sub-sets (if any) originated by the entity
 - Specification of the relationships connecting the entity with other entities of the schema. Each specification is organised as follows:
 - Name of the entity which is connected through the relationship
 - Cardinality (minimum and maximum) of the originating entity in the relationship
 - Purpose of the relationship, in terms of its semantical meaning
 - Attributes (if any) specific of the relationship
 - Entities which are sub-entities of a hierarchy or sub-sets of an entity are supposed to inherit all attributes and relationships of the originating entity and -therefore- are not specified in detail in the text.
 - Relationships representing only classifications of entities (i.e. defined as “is classified by/classifies” in the diagram) are not explicitly defined in the textual description.

NOTE 2 The purpose of the middleware in the overall frame of the architecture is to provide common services to the rest of the system. As a consequence, it may include, in principle, any type of functionality, defined on the basis of the technological, application and organisational requirements of the individual installation.

In this European Prestandard, the scope of the six HCS's identified is limited to the maintaining of the fundamental classes of information, considered to be essential and common in the whole information system. As a consequence, all services specified to be provided by each HCS present similar characteristics, related to the sole basic manipulation of the individual information classes.

For that reason, in order to avoid unnecessary repetition of text, the characteristics of the services which shall be provided by each HCS have been collectively defined in Clause 14 of this European Prestandard standard.

7 Subject of Care Healthcare Common Services (S-HCS)

7.1 Scope

This HCS groups those services which support the rest of the healthcare information system in the identification of subject of care and in the storing and retrieval of the summary personal, administrative and epidemiological data on the individual subjects of care.

The purpose of such information relates to the support of the fundamental administrative and organisational needs of the healthcare organisation with respect to the identification of the subjects of care, the administrative and organisational interactions with the subjects of care and with the external organisations and the statistical, epidemiological and healthcare analyses carried out locally as well as throughout different healthcare organisations.

The main classes of information managed by the Subject of Care Healthcare Common Services (S-HCS) shall relate to

- SUBJECT OF CARE;
- CONTACT;
- CASE.

The information managed by the services of the S-HCS for each SUBJECT OF CARE, CONTACT and CASE shall include a set of summary data needed for identification, as well as personal, and administrative data. Additional information may be related to each of these concepts in each healthcare organisation according to national and local regulations and procedures.

7.2 Structural view

7.2.1 Conceptual diagram

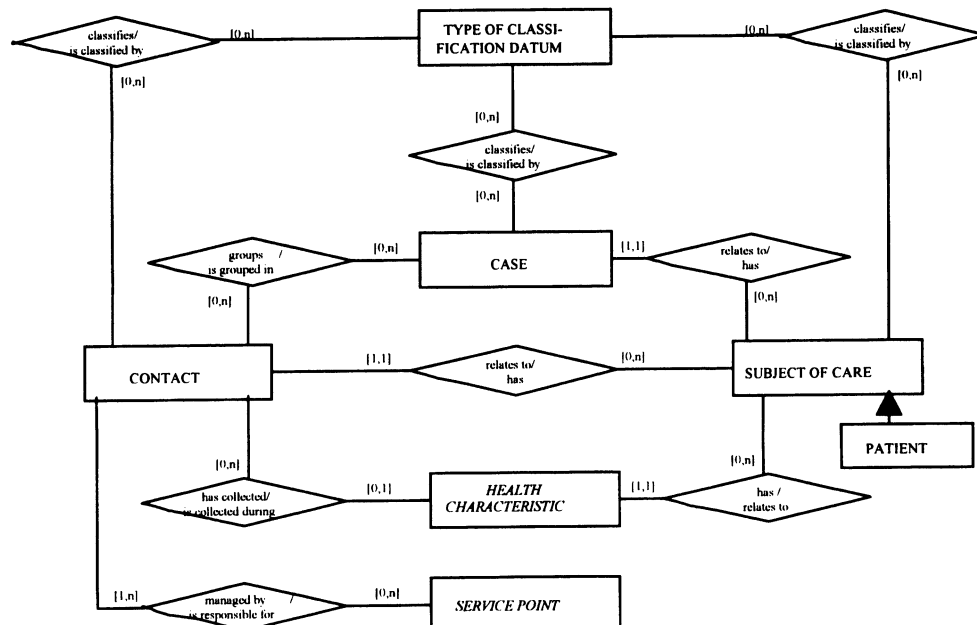


Figure 2 — The conceptual schema of the essential information managed by the Subject of Care Healthcare Common Services

7.2.2 Specification of the individual entities

7.2.2.1 Entity: TYPE OF CLASSIFICATION DATUM

Definition

Concept used for defining a classification of the data adopted by the healthcare organisation for classifying the subjects of care, the cases and the contacts for epidemiological, demographic and administrative purposes, according to local needs, regulations and standards, in addition to those attributes which are explicitly defined in the relevant entities.

Essential attributes

- Identifier of an overall class of types of classification data
- Identifier of the type of classification datum
- Description of the type of classification datum
- Domain of the possible values which may be accepted by classification data of this type

Relationships with:

SUBJECT OF CARE

relationship: classifies [0,n]

Specifies the individual subjects of care which are classified according to the specific type of classification datum.

attributes: value of the type of classification datum according to which the subject of care is classified.

CONTACT

relationship: classifies [0,n]

Specifies the individual CONTACTS which are classified according to the specific type of classification datum.

attributes: value of the TYPE OF CLASSIFICATION DATUM according to which the CONTACT is classified.

CASE

relationship: classifies [0,n]

Specifies the individual CASES which are classified according to the specific type of classification datum.

attributes: value of the TYPE OF CLASSIFICATION DATUM according to which the CASE is classified.

7.2.2.2 Entity: SUBJECT OF CARE

Definition

Person or defined group of persons receiving or having received healthcare [prENV 12443]

Subsets

PATIENT

Subject of care being a person

Essential attributes

- Class of the subject of care (e.g. patient, other types)
- Identifier of the subject of care
- Name (when applicable)
- Date of birth (when applicable)
- Date of death (when applicable)
- Sex (when applicable)
- Residential address (when applicable)

Relationships with:

CASE

relationship: has [0,n]

Specifies the cases related to the subject of care.

CONTACT

relationship: has [0,n]

Specifies the contacts had by the subject of care.

HEALTH CHARACTERISTIC

relationship: has [0,n]

Specifies the health characteristics available in the healthcare information system on the subject of care.

TYPE OF CLASSIFICATION DATUM	relationship: is classified by [0,n] Specifies the classification data according to which the subject of care is classified. attributes: value of the classification datum with respect to the specific subject of care.
------------------------------	--

7.2.2.3 Entity: CONTACT

Definition

Time interval that the healthcare organisation wishes to register for several organisational, clinical, administrative purposes during which the clinical state of a subject of care is under the active consideration of the healthcare organisation and/or care activities are provided to the subject of care.

NOTE The criteria according to which contacts are defined and managed may vary across organisations, according to the different administrative procedures and national regulations. Normally, a contact is where the subject of care comes into direct contact with the healthcare organisation, but it may also include case conferences and case note reviews where the subject of care is not necessarily present.

Essential Attributes

- Identifier of the contact
- Starting date and time
- Reason for the contact
- End date and time
- Reason for the termination
- Type of contact
- Information of the healthcare actor who has requested the contact
- Information of the healthcare actor who has terminated the contact

NOTE In order to allow the system to manage all fundamental information of contacts originated also by healthcare actors external to the healthcare organisation, a generic “information” attribute and not a formal relationship with AGENTS is defined with respect to the actors who have requested and terminated the contact. Individual installations may extend such information through more formal links, according to the scope of the information system and the characteristics of the healthcare organisation.

Relationships with: CASE

relationship: is grouped in [0,n]
Specifies the Cases into which the Contact is grouped.

HEALTH CHARACTERISTIC

relationship: has collected [0,n]
Specifies the health characteristics collected during the contact.

SERVICE POINT

relationship: managed by [1,n]
Specifies the service points which are/have been responsible of the treatment of the contact.
attributes: responsibility start date and time; responsibility end date and time

SUBJECT OF CARE

relationship: relates to [1,1]
Specifies the SUBJECT OF CARE to which the CONTACT relates.

TYPE OF CLASSIFICATION DATUM

relationship: is classified by [0,n]
Specifies the classification data according to which the contact is classified.
attributes: value of the classification datum

7.2.2.4 Entity: CASE

Definition

Aggregation of several contacts, clustered according to specific clinical and/or organisational purposes of the organisation.

Essential Attributes

- Identifier of the case

- Description of the case
- Starting date and time
- Reason for the starting of the case
- Information of the healthcare actor who has initiated the case
- End date and time
- Reason for the termination
- Information of the healthcare actor who has terminated the case

NOTE In order to allow the system to manage all fundamental information of contacts originated also by healthcare actors external to the healthcare organisation, a generic “information” attribute and not a formal relationship with AGENTS is defined with respect to the actors who have requested and terminated the contact. Individual installations may extend such information through more formal links, according to the scope of the information system and the characteristics of the healthcare organisation.

Relationships with:
CONTACT

relationship: groups [0,n]
Specifies the contacts grouped into the case.

SUBJECT OF CARE

relationship: relates to [1,1]
Specifies the subject of care to whom the case relates.

TYPE OF CLASSIFICATION DATUM

relationship: is classified by [0,n]
Specifies the classification data according to which the case is classified.
attributes: value of the classification datum

7.3 Functional view

For each entity defined in the structural view, the S-HCS shall provide the rest of the healthcare information system, with at least, a set of services as defined in Clause 14.

8 Health Characteristic Healthcare Common Services (HC-HCS)

8.1 Scope

This HCS groups the services responsible for the management of the health characteristics on the subjects of care of interest for the healthcare centre.

The information managed by the HC-HCS shall include the description and classification of the various types of health characteristics as well as the actual data relating to the values of such characteristics for the individual subject of care. Health characteristics may be either elementary, for example relating to one single value, or structured for example comprising other elementary or, recursively, structured health characteristics.

The classification criteria defined through the HC-HCS shall conform and refer to taxonomies and coding criteria defined for the individual specialities, according to applicable standards and regulations at national and international level.

The properties for example structure, values, of the individual health characteristics shall be defined in individual installations through the concepts managed by these Healthcare Common Services, on the basis of international standards, national regulations and specific needs of the individual users.

Individual health characteristics may also represent result of the execution of activities. As defined in the specification of the Activity Healthcare Common Services, one health characteristic may represent the result of one individual activity, as well as the result of a combined group of activities for example multiple report.

At least three levels of status, Preliminary, Validated, Annulled, shall be possible for each health characteristic:

— **Preliminary**

representing preliminary information, being unofficial, and whose validity is both limited over time and locally within the organisational unit which is collecting or generating them;

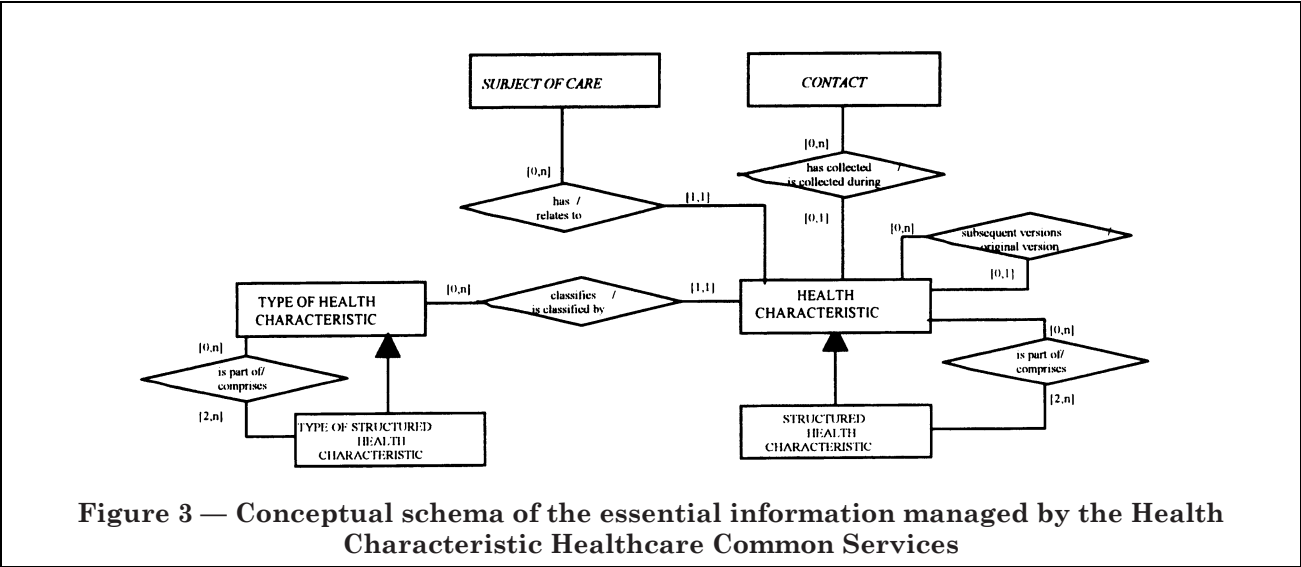
— **Validated**

official information;

— Annulled
information replaced through a later version.

8.2 Structural view

8.2.1 Conceptual diagram



8.2.2 Specification of the individual entities

8.2.2.1 Entity: TYPE OF HEALTH CHARACTERISTIC

Definition

Concept used to classify the health characteristics which are managed by the healthcare organisation. Types of health characteristics may be either elementary information items or structured groups of other types of health characteristics.

Subsets TYPE OF STRUCTURED HEALTH CHARACTERISTIC Type of health characteristic consisting of a structured composition of other types of health characteristics

Essential attributes

- Identifier of an overall class for types of health characteristics
- Identifier of the type of health characteristic
- Identifier whether the types of health characteristic is structured or not
- Domain of the possible values which can be assumed
- Unit of measure and coding criteria adopted in the registration of the actual values

Relationships with:

TYPE OF STRUCTURED HEALTH CHARACTERISTIC

relationship: is part of [0,n]
Defines the Types of Structured health characteristics in which this type (either being structured itself or not) may be comprised
attributes: rules (e.g. sequence position) specifying the role of the health characteristic in the structured type

8.2.2.2 Entity: HEALTH CHARACTERISTIC

Definition:

Element of information describing certain aspects of the health status of one SUBJECT OF CARE, that is considered relevant by the healthcare organisation and is registered in the Healthcare Information System

Subsets	STRUCTURED HEALTH CHARACTERISTIC:	Health characteristic consisting of a structured composition of other of health characteristics
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Essential attributes

- Identifier of the health characteristic
- Status of the health characteristic i.e. Preliminary, Validated, Annulled
- Date and time of the event through which the health characteristic has been generated or collected
- Identification of the healthcare actor who has generated or collected the health characteristic
- Date and time of the event through which the health characteristic has been finally validated
- Identification of the healthcare actor who has finally validated the health characteristic
- Version of the health characteristic (to permit the management of subsequent modifications)
- Actual value of the health characteristic

Relationships with:

STRUCTURED HEALTH CHARACTERISTIC

relationship: is part of [0,n]

Specifies the structured health data in which the health characteristic is comprised.

attributes: rules (e.g. sequence position) specifying the role of the health characteristic in the structured type

HEALTH CHARACTERISTIC

relationship: original version [0,1]

Specifies the original health characteristic of which the instance is a subsequent version.

HEALTH CHARACTERISTIC

relationship: subsequent versions [0,n]

Groups the sequence of subsequent versions of the health characteristic.

CONTACT

relationship: is collected during [0,1]

Specifies the contact during which the health characteristic has been collected.

SUBJECT OF CARE

relationship: relates to [1,1]

Specifies the subject of care to whom the health characteristic relates.

8.3 Functional view

For each entity defined in the structural view, the HC-HCS shall provide to the rest of the healthcare information system, at least, a set of services as defined in Clause 14.

9 Activity Healthcare Common Services (A-HCS)

9.1 Scope

This HCS groups the services supporting the classification and management of the information related to the activities carried out in the various areas of the organisation, both in terms of their description, and as relates the life-cycle of the activities actually performed.

Essential services provided by the A-HCS shall allow the description and maintenance of the following types of information:

- structuring of the healthcare organisation into a set of service points, representing organisational elements, for example individuals or complete units, each of them capable of performing certain types of activities;

- classification and description of the various types of activities which can be performed by the organisational elements, including clinical and organisational aspects such as mutual dependencies, utilisation of resources;
- management of information relating to the individual activities actually performed (autonomously as well as in relationship with the related subject of care), and to the structuring of their life-cycle into a set of statuses, depending on the characteristics of the specific activity being performed and on the rules of the specific healthcare organisation;
- classification and the actual performing complete protocols, representing of clusters of activities grouped by the organisation for different purposes for example organisation, clinical, managerial, technical;
- clustering of the requesting of multiple activities into aggregations called requests;
- classification and the specification of the results of the performed activities, which according to the type of activity and shall represent either health characteristics related to the involved subject of care, or generic (non health characteristics) results, nevertheless relevant for the information system of the organisation.

9.2 Structural view

9.2.1 Conceptual diagram

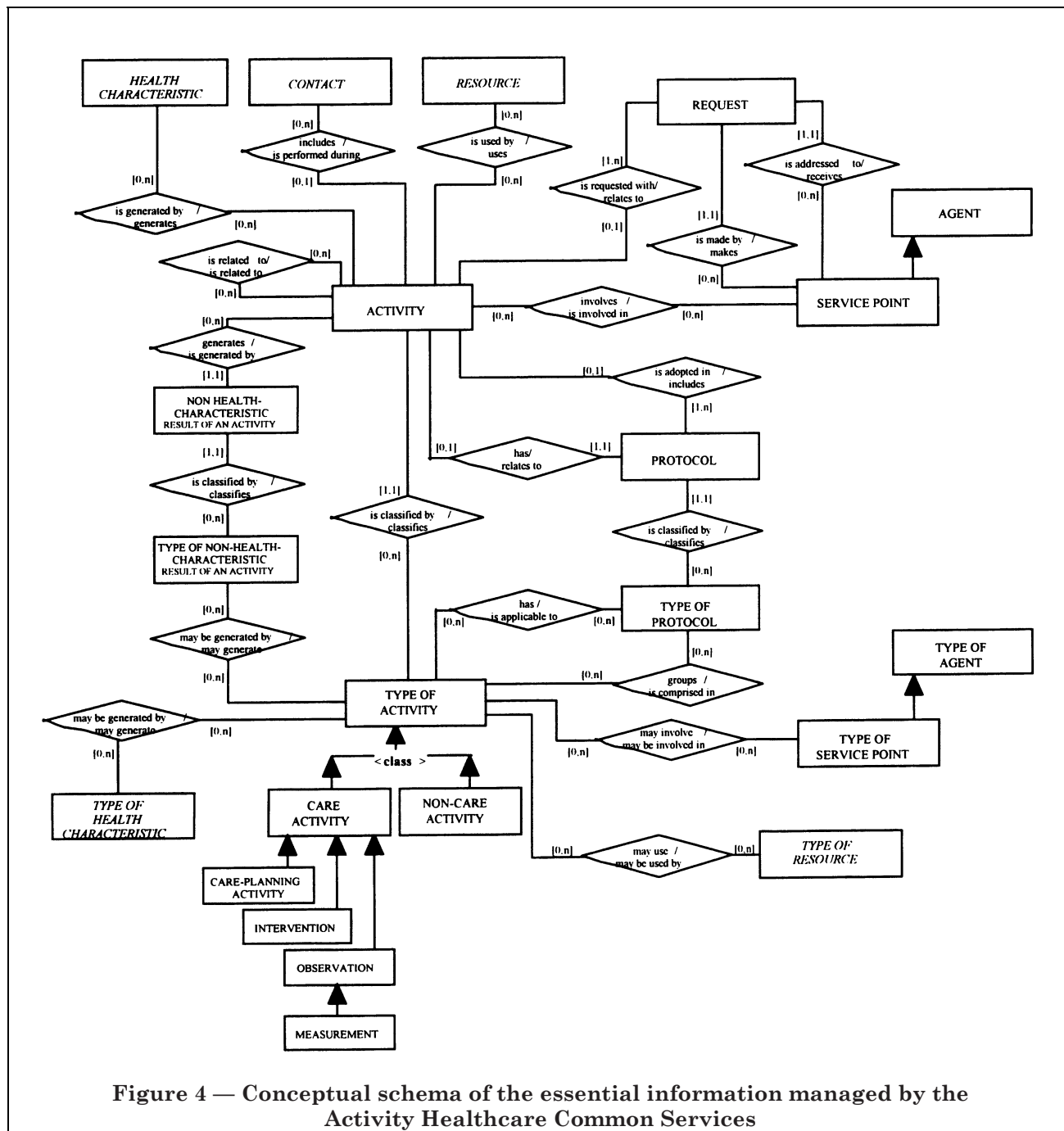


Figure 4 — Conceptual schema of the essential information managed by the Activity Healthcare Common Services

9.2.2 Specification of the individual entities

9.2.2.1 Entity: TYPE OF ACTIVITY

Definition

Concept used to classify the ACTIVITIES which may be performed by the healthcare organisation and whose evolution life-cycle is considered relevant to be monitored and recorded by the organisation.

Sub-entities	CARE ACTIVITY	Activity which intends to improve or increase knowledge of the conditions of a SUBJECT OF CARE
	NON-CARE ACTIVITY	Activity directed towards something different than improving or increasing knowledge of the conditions of a SUBJECT OF CARE

Essential attributes

- Class of type of activity (i.e. CARE ACTIVITY or NON-CARE ACTIVITY)
- Identifier of the subset of Care Activity (only for types of activity of class CARE ACTIVITY)
- Identifier of possible sub-classes (when applicable)
- Identifier of the type of activity
- Description of the type of activity
- Average cost for the execution of activities of this type

Relationships with:

TYPE OF HEALTH CHARACTERISTIC	relationship: may generate [0,n] Specifies the types of health characteristics which may be generated though the execution of this type of activity.
TYPE OF NON-HEALTH CHARACTERISTIC	relationship: may generate [0,n]
RESULT OF AN ACTIVITY	Specifies the information -not considered by the organisation as health characteristics — which may be generated though the execution of this type of activity.
TYPE OF PROTOCOL	relationship: is comprised in [0,n] Specifies the possible types of protocols into which activities of this type may be comprised.
TYPE OF PROTOCOL	relationship: has [0,n] Specifies the possible types of protocols applicable for the execution of this type of activity.
TYPE OF RESOURCE	relationship: may use [0,n] Specifies the default criteria relating to the utilisation of the various types of resources during the various phases of the life-cycle of activities of this type. attributes: quantity of type of resource normally used for this type of activity, rules for utilisation of the type of resource
TYPE OF SERVICE POINT	relationship: may involve [0,n] Specifies the default criteria relating to the involvement of the various service points of the organisation during the life-cycle of activities of this type. attributes: role of the type of service point in the life cycle of the type of activity (e.g. requester, performer, addressee for the report, etc.), rule of involvement.

9.2.2.2 Entity: TYPE OF PROTOCOL

Definition

Concept used to classify PROTOCOLS, i.e. sets of activities grouped by the organisation on the basis of different criteria e.g. clinical, organisational, managerial, technical.

Essential attributes

- Identifier of a generic class of types of protocols
- Identifier of the type of protocol
- Description of the type of protocol

Relationships with: TYPE OF ACTIVITY

relationship: is applicable to [0,n]
Specifies the possible types of activity for whose execution this type of protocol is applicable.

TYPE OF ACTIVITY

relationship: groups [0,n]
Specifies the possible types of activity which may be comprised in the execution of this protocol.

9.2.2.3 Entity: TYPE OF NON-HEALTH CHARACTERISTIC RESULT OF AN ACTIVITY

Definition

Concept used to classify the results which may be generated upon execution of the activities and which do not represent health data related to one subject of care.

Essential attributes

- Identifier of an overall class
- Identifier
- Domain of possible values which can be assumed by the individual result
- Unit of measure and coding criteria adopted in the registration of the actual result

Relationships

TYPE OF ACTIVITY

relationship: may be generated by [0,n]
Specifies the types of activities whose execution may lead to the generation of this type of results.

9.2.2.4 Entity: TYPE OF SERVICE POINT

Definition

Concept, subset of type of agent, used to classify the service points into which the healthcare organisation is structured.

Essential attributes

- Identifier of an overall class
- Identifier of the type of service point
- Description

Relationships with:

TYPE OF ACTIVITY

relationship: may be involved in [0,n]
Specifies the types of activity during whose life-cycle service points of this type may be involved, and the relevant involvement criteria.
attributes: role of the type of service point in the life cycle of the type of activity e.g. requester, performer, addressee for the report, rule of involvement.

9.2.2.5 Entity: SERVICE POINT

Definition

Subset of agents, representing a functional aggregation in the healthcare organisation, which is clearly identifiable, capable of executing a certain set of activities and able to be scheduled according to certain criteria

Essential attributes

- Identifier of the service point
- Description of the service point

Relationships with: ACTIVITY

relationship: is involved in [0,n]
Specifies the individual activities during whose life-cycle the service point has been involved, with the relevant involvement reason.

attributes: role of the service point in the life cycle of the activity (e.g. requester, performer, addressee for the report, etc.)

REQUEST

relationship: receives [0,n]
Specifies the requests received by the service point.

REQUEST

relationship: makes [0,n]
Specifies the requests made by the service point.

9.2.2.6 Entity: ACTIVITY

Definition

Something which is consciously done, in order to achieve particular results.

Essential attributes

- Identifier of the activity
- Status of the activity in its life-cycle
- Date and time of the request
- Date and time requested for the execution
- Date and time of the actual starting of the execution of the activity
- Date and time of the completion of the execution of the activity
- Date and time of completion of the reporting of the activity
- Signature of the individual who has requested the activity
- Signature of the individual who has executed the activity
- Actual cost of execution
- Reason for the execution of activity
- Level of urgency in the execution of the activity

Relationships with: ACTIVITY

relationship: is related to [0,n]
Specifies other individual activities with which the activity is related for certain reasons.

attributes: reason for the relationship between the two activities (e.g. interdiction, time dependency.)

CONTACT

relationship: is performed during [0,1]
Specifies the contact during which the activity has been performed.

HEALTH CHARACTERISTIC

relationship: generates [0,n]
Specifies the health characteristics of a subject of care generated through the execution of the activity.