INTERNATIONAL STANDARD

ISO 12967-1

First edition
2009-08-15

Health informatics — Service architecture —

Part 1: Enterprise viewpoint

Informatique de santé — Architecture de service —

Partie 1: Point de vue d'entreprise

Reference number
ISO 12967-1:2009(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 12967-1 was prepared by Technical Committee ISO/TC 215, *Health informatics*, based on the European Standard EN 12967-1:2007 with minor editorial amendments.

ISO 12967 consists of the following parts, under the general title *Health informatics — Service architecture*:

— *Part 1: Enterprise viewpoint*

— *Part 2: Information viewpoint*

— *Part 3: Computational viewpoint*

Introduction

The healthcare organizational structure consists of networks of centres (hospital cooperations within, for example, counties, individual hospitals, clinics, etc.) distributed over the territory, characterized by a high degree of heterogeneity and diversity, from organizational, logistic, clinical, technological and even cultural perspectives. The structure of individual centres evolves from a vertical, aggregated organization towards the integration of a set of specialized functional areas (e.g. unit of laboratory analyses, unit of surgery), with specific needs and characteristics, nevertheless needing to share common information and to operate according to integrated workflows. Such a situation determines two main needs which conflict with each other in a certain way. On the one hand it is necessary to effectively support 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 organization, at local and territorial levels. This integration requirement is not only related to the need for improving clinical treatments to the subject of care but is also demanded by the urgent necessity of all countries to control and optimize the current level of expenditure for health, whilst ensuring the necessary qualitative level of services to all subjects of care.

The large number of databases and applications, mutually isolated and incompatible, which are already available on the market and operational in healthcare organizations to support specific needs of users, cannot be underestimated. Even within the same centre, healthcare information systems are frequently fragmented across a number of applications, data and functionalities, isolated and scarcely consistent with each other.

In the present circumstances, the main need for care delivery organizations is to integrate and to make available the existing information assets, and to make possible the integration and interoperability of existing applications, thereby protecting investments. During integration activities, continuity of service needs to be achieved whilst gradual migration of existing proprietary, monolithic systems towards the new concepts of openness and modularity occurs. The cost-effectiveness of the solutions, especially when projected on the scale of the whole healthcare organization, represents another crucial aspect to be evaluated carefully.

The goal can be achieved through a unified, open architecture based on middleware independent from specific applications and capable of integrating common data and business logic and of making them available to diverse, multi-vendor applications through many types of deployment. According to the integration objectives at organizational level, all aspects (i.e. clinical, organizational and managerial) of the healthcare structure must be supported by the architecture, which must therefore be able to comprise all relevant information and all business workflows, structuring them according to criteria and paradigms independent from specific sectorial aspects, temporary requirements or technological solutions.

Standards and technological solutions already exist and will continue to be defined for supporting specific requirements, both in terms of *in situ* user operations and with respect to the movement of information. The architecture must be able to accommodate such requirements by allowing the specific models to be integrated with the complete information assets of the healthcare organization and the communication messages to be “services” extracting or importing data from/to the common information shown in Figure 1.

On the basis of these considerations, the purpose of ISO 12967 is twofold:

— identify a methodology to describe healthcare information systems through a language, notation and paradigms suitable to facilitate the planning, design and comparison of systems;

— identify the fundamental architectural aspects enabling the openness, integration and interoperability of healthcare information systems.

The architecture is therefore intended as a basis both for working with existing systems and for the planning and construction of new systems.

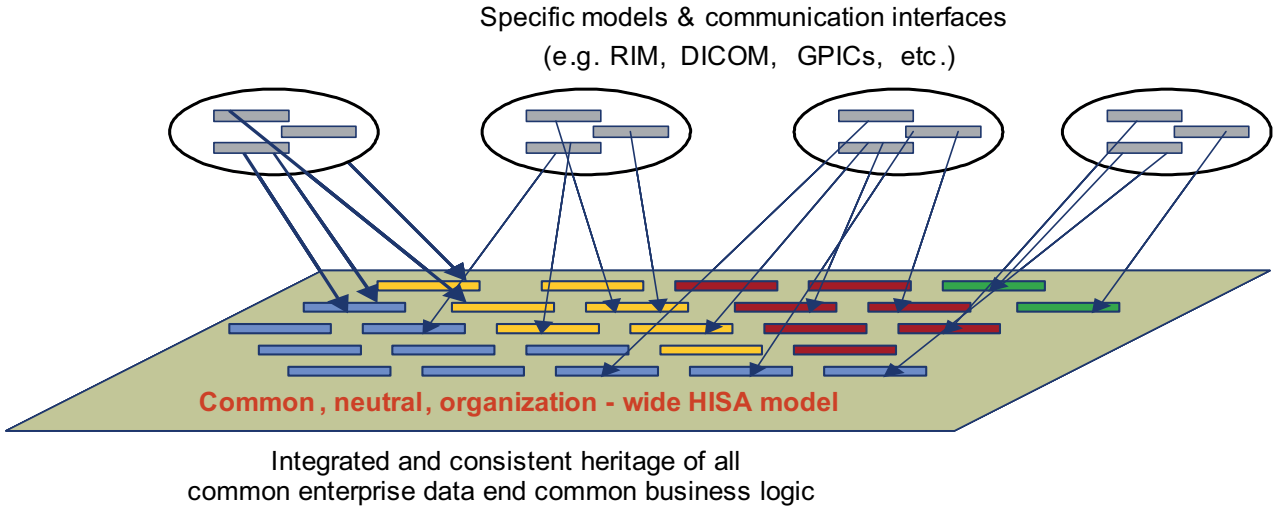

Figure 1 — Complementarity and positioning of the architecture with other standards and models

It is pointed out that ISO 12967 does not aim to define a unique model for clinical, organizational, managerial or administrative activities, but rather defines a set of workflows, information and services common to all healthcare information systems, relevant for any healthcare sector and usable by any application also for facilitating the mutual interworking.

Similarly, ISO 12967 does not aim to represent a final, complete set of specifications. On the contrary, it formalizes only fundamental aspects, identified as common in all countries and considered to be currently essential in any advanced healthcare information system. Specifications are formalized, avoiding any dependency on specific technological products and/or solutions.

ISO 12967, therefore, is an open framework that, according to the specification methodology and preserving the compatibility with previous versions, can be extended during time according to the evolution of the healthcare organization both in the individual (national and local) contexts and through international standardization initiatives.

A European pre-standard, ENV 12967-1, developed according to such rationale during 1993 to 1997 and published in 1998, was the basis for implementations of middleware products and implemented integrations in healthcare regions in several countries. In 2000, the CEN/TC 251 Short Strategic Study on Health Information Infrastructure identified a number of other new architectures and health infrastructure initiatives, as well as the requirements and possibilities for alignment with the large body of information model standards developed by CEN for various communication purposes. European standardization initiatives have delivered a number of object-oriented domain models and message descriptions that include an architecture for the Electronic Health Record (ISO 13606). Cooperation between CEN and HL7 was started in the year 2000, and on the basis of the CEN modelling principles and the HL7 Reference Information Model, this led to the definition of a set of “General Purpose Information Components” (GPICs) usable for developing messages.

The formal major revision of the pre-standard to a European standard was started in 2003 and in 2007 this led to the publication of the EN 12967 Parts 1 to 3 series on which ISO 12967 is based.

The following characteristics of ISO 12967 can be highlighted as follows.

— The architecture is described according to the methodology of ISO/IEC 10746 (all parts), to provide a formal, comprehensive and non-ambiguous specification suitable to serve as a reference in the planning, design and implementation of healthcare information systems.

— The scope of the architecture comprises the support to the activities of the healthcare organization as a whole, from the clinical, organizational and managerial point of view. It therefore does not detail specificities of different subdomains, but provides an overarching comprehensive information and services framework to accommodate requirements.

— The architecture is intrinsically compatible, complementary and synergistic with other models and standards, such as HL7 RIM, the derived GPICs and the Electronic Health Record Architecture ISO 13606. A separate mapping document between this HISA standard and HL7 RIM was produced during the ISO process. Specific information objects and services are explicitly foreseen in the architecture to facilitate the implementation of views and communication mechanisms based on such standards.

— Many of the basic concepts of ISO 12967 are aligned with EN 13940, *Health informatics — System of concepts to support continuity of care* that, in June 2008, it was agreed to process also as an International Standard.

ISO 12967 consists of three parts:

— Part 1 (this part) specifies the overall characteristics of the architecture, formalizes the specification methodology and the conformance criteria, and provides details of the enterprise viewpoint of the architecture;

— Part 2 specifies the information viewpoint of the architecture;

— Part 3 specifies the computational viewpoint of the architecture.

Each part is self-consistent and is also independently utilizable for the intended purposes by different types of users (this part being more oriented to the managerial level, Parts 2 and 3 being more dedicated to the design activities). Nevertheless, it must be understood that they represent three aspects of the same architecture. Mutual references therefore exist between the different parts and evolutions of the individual documents must be carried out according to the defined methodology to preserve the overall integrity and consistency of the specification.

The overall architecture is formalized according to ISO/IEC 10746 (all parts) and is therefore structured through the following three viewpoints.

a) Enterprise viewpoint: specifies a set of fundamental common requirements at enterprise level with respect to the organizational purposes, scopes and policies that must be supported by the information and functionality of the middleware. It also provides guidance on how one individual enterprise (e.g. a regional healthcare authority, a large hospital or any other organization where this model is applicable) can specify and document additional specific business requirements, with a view to achieving a complete specification, adequate for the characteristics of that enterprise.

   Enterprise viewpoint is specified in this part of ISO 12967.

b) Information viewpoint: specifies the fundamental semantics of the information model to be implemented by the middleware to integrate the common enterprise data and to support the enterprise requirements formalized in this part of ISO 12967. It also provides guidance on how one individual enterprise can extend the standard model with additional concepts needed to support local requirements in terms of information to be put in common.

   Information viewpoint is specified in ISO 12967-2.

c) Computational viewpoint: specifies the scope and characteristics of the services that must be provided by the middleware for allowing access to the common data as well as the execution of the business logic supporting the enterprise processes identified in the information viewpoint and in this part of ISO 12967. It also provides guidance on how one individual enterprise can specify additional services needed to support local specific requirements in terms of common business logic to be implemented.

   Computational viewpoint is specified in ISO 12967-3.

Health informatics — Service architecture —

Part 1: Enterprise viewpoint

1 Scope

This part of ISO 12967 provides guidance for the description, planning and development of new systems, as well as for the integration of existing information systems, both within one enterprise and across different healthcare organizations, through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the middleware), distinct from individual applications and accessible throughout the whole information system through services, as shown in Figure 2.

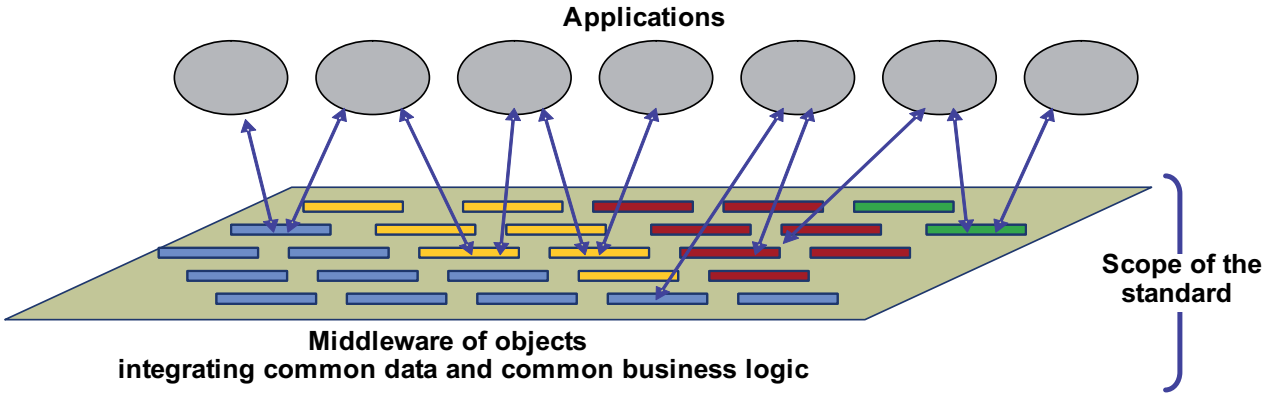

Figure 2 — Scope

This part of ISO 12967 is also independent from, and does not imply either explicitly or implicitly, any specific technological solution or product for its deployment. Accordingly, the formalization of the architecture according to two lower levels of the ODP reference model, the engineering and technology viewpoints, is outside the scope of this part.

The language and notations used here for specifying the architecture are based on UML (Unified Modelling Language) complemented by case studies and other paradigms widely utilized by other standards in health informatics. The level of the specification is complete and non-ambiguous enough to allow its implementation into the specific physical and technological scenarios adopted by the various healthcare organizations and vendors. For this exercise, it is recommended to follow the methodology formalized by the Engineering and Technology viewpoints of the RM ODP Reference model[1)].

1) For more introductory material on RM-ODP and many guideline documents see www.rm-odp.net.

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 10746-1:1998, *Information technology — Open Distributed Processing — Reference model: Overview*

ISO/IEC 10746-2:1996, *Information technology — Open Distributed Processing — Reference model: foundations*

ISO/IEC 10746-3:1996, *Information technology — Open Distributed Processing — Reference model: Architecture*

ISO/IEC 10746-4:1998, *Information technology — Open Distributed Processing — Reference model: Architectural semantics*

3 Terms and definitions

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

3.1 System concepts

3.1.1
scope of a system
behaviour the system is expected to exhibit towards the enterprise it serves

3.1.2
field of application of a specification
properties that the environment of the ODP system must have for the specification of that system to be viable

3.1.3
information service
ability of the system to provide a defined set of output information based on a defined set of input information

NOTE 1 The term information service is consistently used in this part of ISO 12967 for the services provided by the information system.

NOTE 2 The healthcare information services (HCIS) are the healthcare related services provided by healthcare information systems.

3.1.4
viewpoint on a system
abstraction that yields a specification of the whole system related to a particular set of concerns

3.1.5
middleware
enabling technology of enterprise application integration (EAI) describing a piece of software that connects two or more software applications so that they can exchange data

NOTE 1 Common programming interfaces between applications are considered as middleware. For example, Open Database Connectivity (ODBC) enables applications to make a standard call to all the databases that support the ODBC interface.

NOTE 2 HISA services belong to the parts of the architecture that are middleware, and they address basic aspects dealing with the fundamental openness and sharing of information and business logic for the healthcare organization. In this part of ISO 12967, the usage of the term “middleware” is in the context of HISA, related to the services.

3.1.6
enterprise application integration
EAI
use of software and computer systems architectural principles to integrate a set of enterprise computer applications

3.2 Concepts relating to organization

3.2.1
organization
group of people and facilities with an arrangement of responsibilities, authorities and relationships

[ISO 9000:2005]

NOTE 1 The arrangement is generally orderly.

NOTE 2 An organization can be public or private.

NOTE 3 This part of ISO 12967 deals with healthcare organizations ranging from hospital cooperations within, for example, counties, in individual hospitals, individual clinics, etc. encompassing only specific subsets of normal hospital services.

3.2.2
organizational structure
arrangement of responsibilities, authorities and relationships between people

NOTE 1 The arrangement is generally orderly.

NOTE 2 A formal expression of the organizational structure is often provided.

NOTE 3 The scope of an organizational structure can include relevant interfaces to external organizations.

3.3 Community concepts

3.3.1
community
configuration of objects formed to meet an objective

NOTE The objective is expressed as a contract, which specifies how the objective can be met

3.3.2
federation
community of domains

3.3.3
objective
practical advantage or intended effect, expressed as preferences about future states

NOTE 1 Some objectives are ongoing, some are achieved once they are met.

NOTE 2 In the text of ITU-T Rec. X.903 (in ISO/IEC 10746-3:1996) the terms purpose and objective are synonymous. The enterprise language systematically uses the term, objective, and emphasizes the need for expressing objective in measurable terms.

3.3.4
community object
composite enterprise object that represents a community

NOTE The components of a community object are objects of the community represented.

3.4 Behaviour concepts

3.4.1
actor with respect to an action
enterprise object that participates in the action

NOTE It may be of interest to specify which actor initiates that action.

3.4.2
artefact with respect to an action
enterprise object that is referenced in the action

NOTE An enterprise object that is an artefact in one action can be an actor in another action.

3.4.3
resource
enterprise object which is essential to some behaviour and which requires allocation or may become unavailable

NOTE 1 Allocation of a resource may constrain other behaviours for which that resource is essential.

NOTE 2 A consumable resource may become unavailable after some amount of use or after some amount of time (in case a duration or expiry has been specified for the resource).

3.4.4
interface role
role of a community identifying behaviour which takes place with the participation of objects that are not members of that community

3.4.5
process
set of interrelated or interacting activities which transforms inputs into outputs

[ISO 9000:2005]

NOTE 1 Inputs to a process are generally outputs of other processes.

NOTE 2 Processes in an organization are generally planned and carried out under controlled conditions to add value.

NOTE 3 A process where the conformity of the resulting product cannot be readily or economically verified is frequently referred to as a “special process”.

NOTE 4 An important objective for health care today is its ability to be organized in integrated processes to ensure continuity of care. The processes may be considered within a single organization or across organizations.

NOTE 5 The health care process is provided in the health care enterprise.

NOTE 6 When a demand for care is accepted by a health care provider, a care mandate is established stating the mission and authorization for the health care provider to provide health care services to the subject of care. This care mandate is the basis for decisions about which health care activities are to be performed, what the objective is for the health care process and the receptacle for objective evidence provided by the clinical process. Through verification, the quality of each health care activity or series of health care activities can be assessed giving prerequisites for possible rework, repair, scrap or concession [ISO 9000:2005 definitions 3.6.7, 3.6.9, 3.6.10, and 3.6.11, respectively]. The mandate finally reaches a point where the total requirement for the health care process has been fulfilled and the care mandate can be terminated.

NOTE 7 In the clinical process, the health may improve, a risk for deterioration of the health may be reduced, or knowledge about the health may be improved, something which increases the possibilities to have a positive influence on the health.

NOTE 8 Processes can be influenced by events. Such an event does not occur within the process in question, but is the conception by the process of an activity executed in another process. An event will probably lead to a change in the decided process strategy or to a result of the process other than the intended one.

NOTE 9 ISO 10746-1 defines process as: a collection of steps taking place in a prescribed manner and leading to an objective.

3.4.6
step
abstraction of an action, used in a process, that may leave unspecified objects that participate in that action

3.4.7
service
number of processes, involving the organization in the provision of specific objectives

NOTE 1 This definition regards the services provided in the organization, with or without an electronic information system, whereas the definition of “Information service” regards the information (input/output) provided by the system.

NOTE 2 The healthcare services are the services taking place within a healthcare organization

3.4.8
workflow
number of services, involving the organization in the provision of more complex objectives, according to agreed procedural rules

NOTE In healthcare, the workflow will often take place based on three fundamental processes: the clinical process, the communication process and the management process, where information, tasks and activities are shifted between these.

3.5 Policy concepts

3.5.1
policy
set of rules related to a particular purpose

NOTE 1 A rule can be expressed as an obligation, an authorization, permission or a prohibition

NOTE 2 Not every policy is a constraint. Some policies represent an empowerment.

NOTE 3 This definition may be refined by adding authorization.

3.5.2
authorization
prescription that a particular behaviour must not be prevented

NOTE Unlike permission, an authorization is an empowerment

3.5.3
violation
action contrary to a rule

NOTE A rule or policy may provide behaviour that is to occur upon violation of that or some other rule or policy.

3.6 Accountability concepts

3.6.1
party
enterprise object modelling a natural person or any other entity considered to have some of the rights, powers and duties of a natural person

NOTE Examples of parties include enterprise objects representing natural persons, legal entities, governments and their parts, and other associations or groups of natural persons.

3.6.2
commitment
action resulting in an obligation by one or more of the participants in the act to comply with a rule or perform a contract

NOTE The enterprise object(s) participating in an action of commitment may be parties or agents acting on behalf of a party or parties. In the case of an action of commitment by an agent, the principal becomes obligated.

3.6.3
declaration
action that establishes a state of affairs in the environment of the object making the declaration

NOTE The essence of a declaration is that, by virtue of the act of declaration itself and the authority of the object or its principal, it causes a state of affairs to come into existence outside the object making the declaration.

3.6.4
delegation
action that assigns authority, responsibility or a function to another object

NOTE A delegation, once made, may later be withdrawn.

3.6.5
evaluation
action that assesses the value of something

NOTE 1 For example, the act by which an ODP system assigns a relative status to something, according to an estimation by the system.

NOTE 2 Value can be considered in terms of usefulness, importance, preference, acceptability, etc; the evaluated target may be, for example, a credit rating, a system state, a potential behaviour, etc.

3.6.6
prescription
act that establishes a rule

NOTE Specialized meaning in healthcare where a prescription of medicinal products establishes the rule that medication can be given by a pharmacy

3.6.7
agent
enterprise object (authority, responsibility, function, etc.) that has been delegated by and acts for another enterprise object (in exercising the authority, carrying out the responsibility, performing the function, etc.)

NOTE 1 An agent may be a party or may be the ODP system or one of its components. Another system in the environment of the ODP system may also be an agent.

NOTE 2 The delegation may have been direct, by a party, or indirect, by an agent of the party having authorization from the party to so delegate.

3.6.8
principal
party that has delegated (authority, a function, etc.) to another

3.6.9
contracting party with respect to a contract
party that agrees to a contract

4 Symbols and abbreviations

ECG Electrocardiogram

EHR Electronic Health Record

HISA Health Informatics Service Architecture

ODP Open Distributed Processing

SOA Service Oriented Architecture

UML Unified Modelling Language

5 Methodology for the specification of the architecture

This clause describes the methodology adopted by this part of ISO 12967 for the specification of the architecture. The same methodology shall be used by healthcare enterprises and industrial vendors for describing the characteristics of HISA-conformant systems. The scope of the methodology is the specification of the contents of the documents that will be delivered for describing the architecture. The formalization of the process according to which a system is identified, planned, designed and implemented is outside the scope of this part of ISO 12967; the ODP approach described in this clause may nevertheless provide guidance for the definition of such a process.

Subclause 5.1 provides an overview on the viewpoint-based ODP methodology. Subclause 5.2 specifies how this is used in HISA (for the enterprise, information and computation viewpoints themselves) and how the characteristics of HISA-conformant systems should be described.

5.1 Viewpoints for the specification of the architecture

The methodology defined by ISO/IEC 10746 (all parts) shall be used for the specification of a healthcare service architecture that shall be structured through five viewpoints, individually specifying a particular set of concerns of the whole system:

— **Enterprise viewpoint**, which is concerned with the purpose, scope and policies governing the activities of the specified system within the organization of which it is a part;

— **Information viewpoint**, which is concerned with the kinds of information handled by the system and constraints on the use and interpretation of that information;

— **Computational viewpoint**, which is concerned with the functional decomposition of the system into a set of objects that interact through formalized interfaces;

— **Engineering viewpoint**, which is concerned with the infrastructure required to support system implementation and distribution;

— **Technology viewpoint**, which is concerned with the choice of technology to support system implementation and distribution.

For each viewpoint there is an associated viewpoint language that can be used to express a specification of the system from that viewpoint. The object modelling concepts give a common basis for the viewpoint languages and make it possible to identify relationships between the different viewpoint specifications and to assert correspondences between the representations of the system in different viewpoints.

This part of ISO 12967 formalizes the enterprise, information and computational viewpoints illustrated in Figure 3. Systems conformant to HISA shall be described by means of the same three viewpoints, complemented with the specification of the infrastructural and technological characteristics. Such aspects should be described according to the criteria defined by the ODP engineering and technology viewpoints.

NOTE An actual implementation of the HISA services could be described as a Service Oriented Architecture (SOA), e.g. in the form of web services.

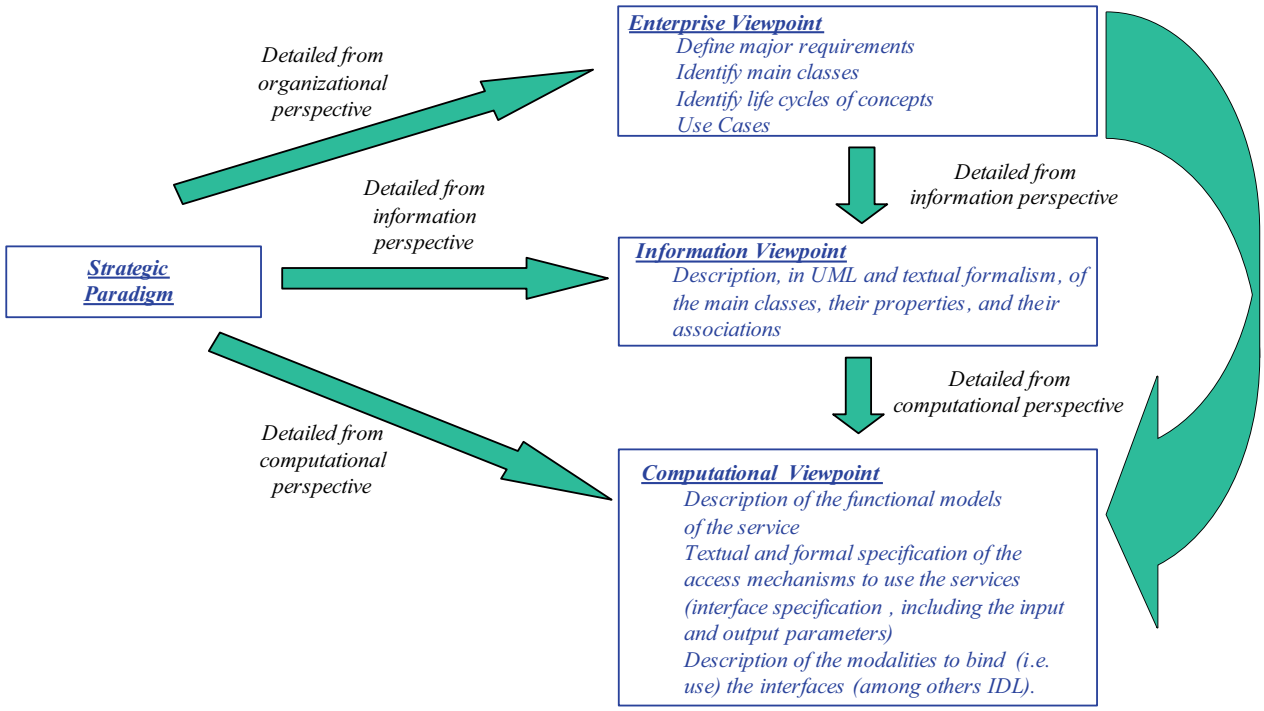

Figure 3 — Three (of five) ODP viewpoints detailed in HISA

5.2 The HISA specification procedure

5.2.1 The Strategic Paradigm

The specification of the architecture shall start with a concise, managerial-oriented document (the “Strategic Paradigm”) that identifies (at a high level of abstraction) the overall requirements and strategic objectives of the envisaged system. It describes, in natural language:

— the rationale and scope of the IT system with respect to the overall enterprise;

— fundamental organizational processes (as defined under terms and definitions) that can be identified in the enterprise and that are relevant for the envisaged system;

— fundamental constraints and objectives to be satisfied.

NOTE Subclause 6.2 further details what the content of a strategic paradigm of an enterprise should include.

By evolving and refining the Strategic Paradigm and conforming to it, the architecture shall then be described through the different viewpoints up to a complete and formal specification of the individual areas of concern, detailed to represent non-ambiguous terms of reference for

— planning of development and evolution processes,

— design and implementation of deployed systems, and

— description and comparison of different products.

The methodology for carrying out the specification includes the following three viewpoints.

5.2.2 Specification of the enterprise viewpoint

An objective of this specification is the formalization of the requirements to be satisfied by the system from the point of view of the target healthcare enterprise and the field of application (of the specification), expressed in terms of user activities to be supported and man-machine interaction according to which such activities shall be supported by the system.

The specification shall be structured hierarchically, through the following three levels of refinement, at least.

1) Identification of the business processes with relevant scope and objectives with regard to the overall mission of the healthcare enterprise.

2) For each process, identification of the tasks carried out by the involved users, with the mutual dependencies and interactions. When identifying such tasks all aspects and requirements of the enterprise (i.e. including the clinical, organizational and managerial characteristics) shall be taken into account.

3) For each task, identification of the information that is used and of the elementary activities that are performed for processing it.

The specification of the information relevant for the task shall include:

a) a non-ambiguous description of the semantics of the information, including the domain of validity of the possible values and the specification of the coding criteria and classifications (if any) to be adopted;

b) identification of the modalities according to which the data are used (i.e. whether they are generated or manipulated or simply acquired by the task);

c) qualitative indication of the level of relevance/criticality of the data with respect to the overall business process;

d) volume of instances envisageable in the whole information assets of the enterprise.

The specification of each elementary activity shall include:

e) a non-ambiguous description of the scope and objectives of the activity with respect to the business process;

f) qualitative indication of the frequency of execution of the activity and on the rapidity of completion required by the organizational context;

g) qualitative indication of the level of relevance/criticality of the activity with respect to the overall business process.

In addition to such a specification of the scope and behaviour of the system from the point of view of the user activities, the enterprise viewpoint shall also include a section with the overall requirements and policies of the target enterprise to be satisfied by the system, including (without being limited to) the technological constraints to be met.

5.2.3 Specification of the information viewpoint

The objective of this specification is the description of the information relevant for the enterprise to be integrated in the middleware. It shall consist of a formal information model detailing the semantic and syntactic aspects of all data to be managed. The information model delivered shall be at a level allowing implementers to derive an efficient design of the system in the specific technological environment that will be selected for the physical implementation.

The specification shall be expressed as an object model. Objects shall be derived from the enterprise viewpoint by properly structuring and aggregating the information that have been identified as relevant in the specification of the overall business processes, tasks and activities. The completeness of the information

model with respect to the information requirements set out by the enterprise viewpoint shall be verified and documented (e.g. by means of a vocabulary with the correspondence between the concepts identified in the two views).

In order to increase the readability of the specification, the document should comprise the following sections:

a) formal modelling criteria adopted and properties common to all classes identified in the model;

b) one schema for each business process identified in the enterprise viewpoint, showing, at a high level of abstraction, the classes relevant for this;

c) specification of the identified objects, with the definition of their properties and of the relations among them.

5.2.4 Specification of the computational viewpoint

The objective of this specification is the description of the services to be provided by the middleware to allow applications to utilize the common objects for manipulating the information and executing the business logic implemented by the objects.

The specification shall consist of a formal model detailing, at least, the scope of the services and the interfaces for their invocation. The model shall be at a level allowing implementers to derive an efficient design of the individual functionalities in the specific technological environment that will be selected for the physical implementation of the system.

The specification shall be expressed as an object model. Objects shall be derived from and consistent with those specified in the information viewpoint by properly structuring and aggregating their properties and methods according to the user activities formalized in the enterprise viewpoint. The completeness of the computational model with respect to the functional requirements set out by the enterprise viewpoint shall be verified and documented (e.g. by means of a vocabulary with the correspondence between the services identified in the computational viewpoint and the activities specified in the enterprise viewpoint).

In order to increase the readability of the specification, the document should comprise the following sections:

a) formal modelling criteria adopted and interfacing mechanisms common to all services identified in the model;

b) one schema for each business process identified in the enterprise viewpoint, showing, at a high level of abstraction, the services relevant for this;

c) specification of the identified services, with the definition of their interfaces and of the information being manipulated.

5.3 Iterative specification

Depending on the complexity of the scope being addressed, the specification process may also proceed iteratively by detailing each viewpoint through multiple, subsequent levels of refinement.

In order to increase the readability and usability of the specification by the different intended users, at least two levels of detail should be provided, as follows.

— Strategic-level specification, mainly oriented to managerial and planning purposes. For each viewpoint, this level of specification shall formalize, in a concise and abstract modality, the fundamental aspects most relevant for the enterprise (i.e. the main business processes and tasks in the enterprise viewpoint, the scope of the principal classes in the information viewpoint and the scope of the services implementing the most crucial business logic in the computational viewpoint).

— Operational-level specification, mainly oriented to design and comparison purposes. This level of specification shall complete the description of each viewpoint, by extending and refining the strategic specification with the detail of all characteristics of the architecture, up to the requested level of completeness and non-ambiguity.

From the operational level specification feedbacks are available, leading to refinements and amendments in the strategic level that will then imply further refinements in the whole process, as shown in Figure 4.

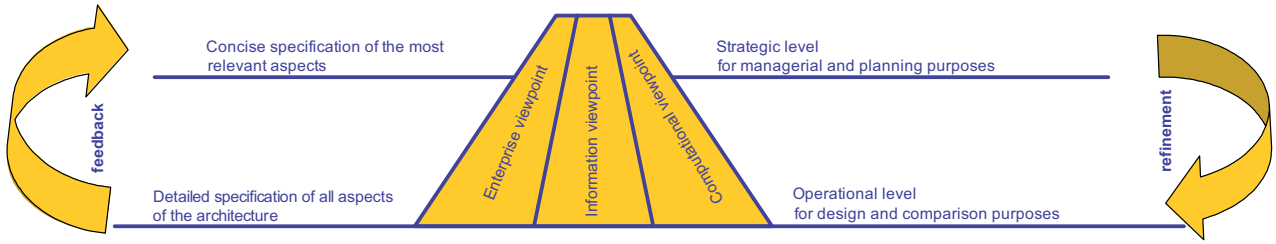

Figure 4 — Iterative, incremental specification process

5.4 Viewpoints specification languages and notations

Each viewpoint of the architecture shall be specified by means of a combination of textual descriptions and formal notations suitable to achieve the objectives of completeness and non-ambiguity set out in 5.1 to 5.3

This part of ISO 12967 does not prescribe the adoption of any specific modelling notation or tool for such specifications.

The utilization of UML-based criteria is nevertheless recommended as described in the following:

— **Enterprise viewpoint**: specified by means of pure text, complemented with use-case diagrams to describe the users' scenarios and swim-lane diagrams to describe the business processes of the healthcare enterprise.

— **Information viewpoint**: described by means of class diagrams detailing the attributes, complemented with textual descriptions.

— **Computational viewpoint**: specified by means of class diagrams detailing the methods, complemented with textual descriptions on the scope and functionalities of each service, the formalization of the data-types used at interface level and by the IDL specification of the interface of each service.

6 HISA overview

NOTE This clause provides an overview of the overall requirements and characteristics of the architecture. The specific aspects will then progressively be refined and specified in the parts of ISO 12967 dealing with the individual viewpoints.

6.1 General requirement

In any healthcare organization that may comprise multiple centres (e.g. clinics), units and individuals, different types of actors need to share common information and to collaborate according to common processes and workflows.

Information and business logic common to different sectors of the healthcare organization shall therefore be integrated in a specific architectural layer (i.e. the middleware) of the information system and shall be accessible through services based on public and stable interfaces, as illustrated in Figure 2

The middleware shall conform to the following requirements.

a) It shall be capable of integrating and accommodating all data and all business logic relevant for the clinical, administrative and managerial activities of the healthcare enterprise.

b) It shall, at least:

   1) support the general requirements identified in the “enterprise viewpoint” of this part of ISO 12967;

   2) implement the information model specified in the “information viewpoint” of this part of ISO 12967;

   3) provide the services specified in the “computational viewpoint” of this part of ISO 12967.

c) It shall be open, both at logical and physical levels, and shall allow extension and evolution according to local requirements, national regulations and to specific applicable standards.

d) It shall represent an autonomous and replaceable set of components of the physical architecture of the information system, separated from other applications.

6.2 Enterprise viewpoint

At a high level of abstraction, the whole healthcare enterprise can be described by means of the following paradigm (as a narrative overview):

In any healthcare organization that may comprise healthcare centres, units, service points and individuals, different types of actors perform activities, related to care delivery, as well as to administrative and managerial requirements of the enterprise.

The execution of an activity usually creates outcomes which may include clinical information (comprising both structured and multimedia data) about the relevant subject(s) of care, as well as other data relevant for the organization.

For the execution of one activity, resources (such as staff members, consumable materials, logistic infrastructures and equipment) are necessary. The involvement of each resource has its specific rules and cost, depending on the specific resource involved, on the logistic constraints and on the characteristics of the activity performed.

Due to the particular nature of the clinical information (either generated from the execution of specific activities, or pre-existing in the system), the management of such data must conform to specific provisions in terms of accountability, validation and traceability. Such data also need to be accessed and aggregated according to the various views and perspectives of the disciplines and users found in the enterprise.

Different types of users are authorized 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.

Due to its relevance to multiple types of users and enterprise processes, the managed information may need to be related to multiple classifications and coding criteria for clinical, organizational and managerial purposes.

Electronic interactions among different organizations and information systems are usually based on messages adhering to communication standards (the generally most used way of inter-system communication, especially for non-service-oriented system architectures).

Through this overall paradigm three fundamental workflows are identified in the users’ activities, which shall be supported by the following services provided by the middleware:

— **Subject of Care workflow (patient-centric)**

This workflow relates to the users’ activities related to the management of the personal and statistical information regarding subjects of care and to the management of encounters of the Subject of Care with the organization itself, including the interactions with the funding organizations.

— **Activity management workflow (carer-centric)**

This workflow relates to users' activities related to the management of the different types of activities that are executed in the organization during their whole life-cycle, including, but not limited to, the aspects related to the initial requesting, the booking, the planning, the execution and the reporting.

— **Clinical information workflow (information-centric)**

This workflow relates to users' activities related to the management of the clinical data, including, but not limited to, the aspects relating to their collection and validation, as well as the aggregation and structuring of the elementary data according to the specific requirements of the different disciplines and users.

Other services of the middleware shall support (both independently and complementary to the above-mentioned workflows) the following clusters of users' activities:

— Management of the information related to the description of the structure of the organization, of the users of the information system, and of the authorization criteria according to which users are allowed to access the data and execute the various functionalities.

— Management of the resources available in the organization, and of the rules and criteria according to which they are available and can be utilized.

— Management of classifications, coding criteria and dictionaries adopted in the different sectors to classify (for clinical, organizational and managerial purposes) the managed information.

The middleware shall also provide services enabling the structuring of data and the interactions with other information systems through mechanisms based on messages and other formalisms conforming to communication standards (e.g. HISA mapping to and exchange with EHR messages).

"HISA Enterprise viewpoint" of this part of ISO 12967 provides a detailed specification of the enterprise requirements that shall be satisfied by the middleware.

6.3 Information viewpoint

The middleware shall integrate and organize in one consistent model the information relevant for the business processes and users' activities identified in the enterprise viewpoint.

According to the requirements identified in the enterprise viewpoint, seven clusters of objects shall be identified in the information model of the middleware, each of them responsible for organizing and storing the information necessary for supporting the users' activities identified in the related areas of the enterprise viewpoint as follows.

1. Subject of care objects
These objects shall organize and store the information necessary for supporting the users' activities identified in the "Subject of Care workflow" of the enterprise viewpoint.

2. Activity management objects
These objects shall organize and store the information necessary for supporting the users' activities identified in the "Activity Management workflow" of the enterprise viewpoint.

3. Clinical information objects
These objects shall organize and store the information necessary for supporting the users' activities identified in the "Clinical Information workflow" of the enterprise viewpoint.

4. Organization, users and authorization objects
These objects shall organize and store the information necessary for supporting the users' activities related to the management of description of the organization, of the users and of the authorizations, as identified in the enterprise viewpoint.

5. Resources objects
These objects shall organize and store the information necessary for supporting the users' activities related to the management of resources, as identified in the enterprise viewpoint.

6. Classification objects
These objects shall organize and store the information necessary for supporting the users' activities related to the management of classifications, coding criteria and dictionaries, as identified in the enterprise viewpoint.

7. Messaging objects
These objects shall organize and store the information necessary for supporting the structuring of data and the communications with other systems through messaging mechanisms, as identified in the enterprise viewpoint.

Such criteria for aggregating the objects of the information model are aimed at increasing the readability of the whole model by establishing a direct relationship with the users activities identified in the enterprise viewpoint. Since the information model shall be integrated and be able to support the whole enterprise activities, mutual relationships and references will exist between the information defined in each group of objects.

"HISA Information viewpoint" of ISO 12967-2 provides a detailed specification of the information model that shall be implemented by the middleware.

6.4 Computational viewpoint

The middleware shall provide services capable of supporting the business processes and users activities identified in the enterprise viewpoint.

With such a view, the middleware shall provide the following services.

a) Basic services, allowing retrieval and manipulation (i.e. addition, modification, deletion) of each instance of each object identified in the information model. They shall represent the fundamental services of the architecture, essential for

— being used directly by applications, to allow them to manipulate the information for their specific purposes (including reporting, statistics, ad-hoc query, etc.),

— being used as building blocks for the complex services,

— assuring the fundamental openness of the system and the ownership of the customer to the information within it.

b) Complex services, implementing complete business transactions related to the supported users' activities, also involving multiple objects and data according to the specific rules of the organization.

"HISA Computational viewpoint" of ISO 12967-3 provides a detailed specification of the services that shall be provided by the middleware.

7 Methodology for extensions

This part of ISO 12967 identifies only a minimal set of requirements, identified (at the current date) to be fundamental and common to all healthcare organizations, that shall be satisfied by the middleware, in terms of enterprise activities to be supported, information to be managed and services to be provided.

The standard specification shall be extensible over time according to the evolution of the applicable standardization initiatives.

Industrial products conforming to the standard specification shall allow extensions to satisfy national and local requirements.

Extensions, both for the evolution of the standard and for satisfying local requirements, shall be formalized according to the methodology defined in Clause 5 of this part of ISO 12967 through the following process:

a) New requirements shall be formalized according to the methodology defined in Clause 5 and compared with the requirements defined in the enterprise viewpoint of the standard, identifying the additional business processes and users' activities to be supported. Such an exercise shall lead to the delivery of an extended version of the enterprise viewpoint.

b) On the basis of the requirements formalized in the extended enterprise viewpoint, the standard information viewpoint shall be extended according to the methodology defined in Clause 5, by introducing additional objects and additional attributes in the already existing objects. Additional objects shall conform to the general provisions for all HISA objects, defined in Clause 6 and in ISO 12967-2. Such an exercise shall lead to the delivery of an extended version of the information viewpoint.

c) On the basis of the requirements formalized in the extended enterprise viewpoint and the objects defined in the extended information viewpoint, the standard computational viewpoint shall be extended according to the methodology defined in Clause 5 by introducing additional services for accessing and manipulating the additional data, as well as for implementing complex user transactions. Additional objects shall conform to the general provisions for all HISA objects, defined in Clause 6 and in ISO 12967-3. Such exercise shall lead to the delivery of an extended version of the computational viewpoint.

Extensions to the architecture shall guarantee the compatibility and the consistency with the provisions of the standard, in the sense that the overall principles defined in Clause 5 and 6 will be satisfied and the services already formalized shall not be changed, either in the scope or in the interface, also in the extended version.

8 Conformance criteria

NOTE Two types of conformance criteria are identified, according to the twofold scope of this part of ISO 12967 for providing both a methodology for describing healthcare information systems and the specification for a middleware capable of supporting the whole information system of the healthcare enterprise.

8.1 Conformance of specification documents to the HISA methodology

The specification for the information system of a specific healthcare enterprise claiming conformance to HISA shall conform to the methodology and shall consist of the documents defined in Clause 5 "Methodology for the specification of the architecture".

The following documents shall be delivered: the strategic paradigm, the enterprise viewpoint, the information viewpoint and the computational viewpoint.

Recommended, optional, complementary documents may describe the physical implementation by means of an engineering viewpoint specification document and of a technology viewpoint specification document, according to the ISO/ODP provisions.

The producer of such documents that should be evaluated for conformance to this part of ISO 12967 may be the healthcare enterprise itself but will often be done in cooperation with a HISA platform product supplier and HISA specialist consultancy companies

8.2 Conformance of middleware products to the HISA architectural requirements

Products claiming conformance to this part of ISO 12967

i) shall be described by means of the methodology and the documents defined in Clause 5 "Methodology for the specification of the architecture",

ii) shall implement middleware conforming to the requirements defined in Clause 6 "HISA overview",

iii) shall implement an information model comprising all objects and conforming to the requirements defined in ISO 12967-2 “HISA Information viewpoint”,

iv) shall provide, at least, all services defined in ISO 12967-3 “HISA Computational viewpoint”.

v) shall be extensible to accommodate local and new standardization requirements according to the criteria defined in Clause 7 “Methodology for extensions”.

The product should, by its realization of HISA, encompass the EHR-related CEN standards and their national implementations [2)] and the main messaging and communication standards defined in the international scenario, according to the actual requirements of the specific healthcare enterprises.

The services of HISA are intended to be seen as a whole needed by healthcare enterprises for developing a complete service architecture. Should suppliers provide only a subset of the HISA services, a partial conformance to the relevant HISA services may be declared. Thus, if addressing only parts of the HISA information model with its services, compliance declaration should define what is included and excluded. As only the top three ODP viewpoints (Enterprise, Information and Computation) are addressed in ISO 12967, compliance is also only required for these (i.e. without engineering and technological viewpoints, related to specific architectures and solutions).

NOTE 1 If several suppliers together provide the total of the HISA service architecture, it is up to them together to declare the conformance as offered to the customers.

NOTE 2 HISA can be adopted incrementally, for example, gradually implementing it in the local architecture and declaring partial conformance.

9 The HISA Enterprise viewpoint

9.1 Introduction (informative)

9.1.1 General

Providing healthcare is a complex task, involving many different actors, each being part of specific specializations of the overall enterprise. Healthcare is organized in many ways, e.g. on geographical levels (from, for example, regions down to general practitioners), as well as into medical specialties.

Healthcare services are provided on many levels, with different purposes and scope.

In the following, the healthcare enterprise is seen from

— a regional, inter-enterprise perspective,

— a medical/clinical perspective, and

— an operational/clinical and organizational process model perspective, e.g. in a hospital.

None of these perspectives provide an exhaustive description of the healthcare enterprise and its services, within the domain as a whole. The focus of this part of ISO 12967 is mainly on the intra-enterprise level and the two last bullets. The descriptions serve to identify common, essential healthcare services.

2) Such as G-EPJ (Denmark)

9.1.2 The regional, inter-enterprise perspective

At a high level of abstraction, Figure 5 presents a simplified model of the actors/stakeholders involved in a regional health system. At the top of the pyramid are patients who need healthcare services. Providers provide these services. Health services are paid either directly or indirectly through third parties. Indirect payment is the preferred way in most health systems and the third party can be a private health insurance agency or a public agency (run by the government, region, municipality or an association of municipalities). The third parties act on behalf of the clients they have insured or the population they are responsible for by negotiating contracts with the health service providers.

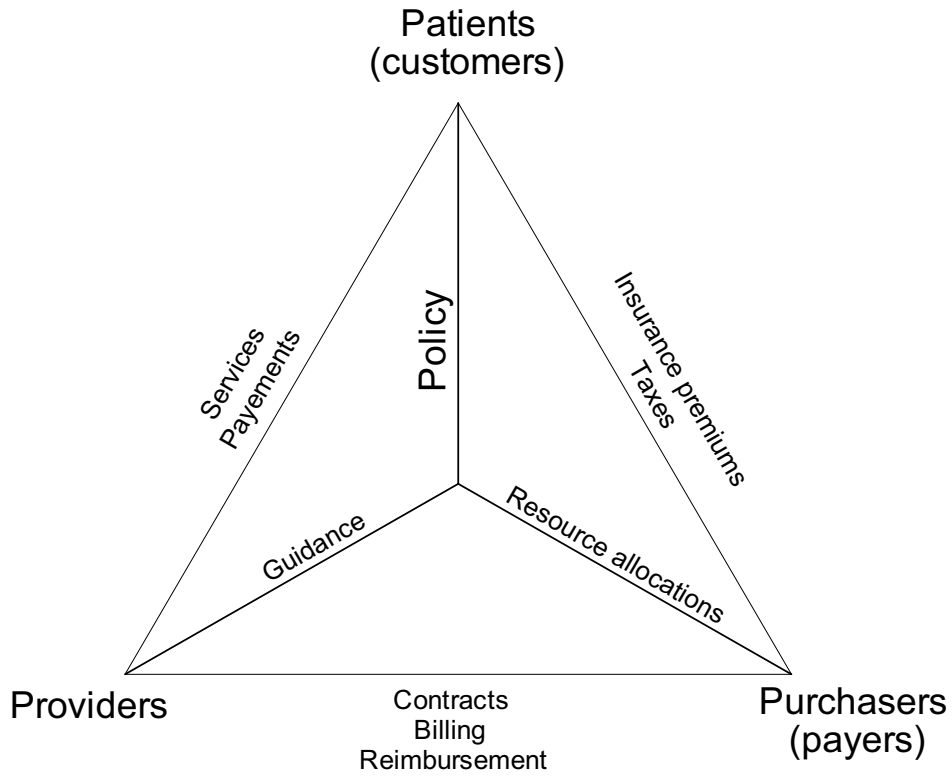

Figure 5 — Actors/stakeholders of a regional health system and their relations

9.1.3 The medical/clinical perspective

On the level of the clinical process itself, the following Figure 6 presents one conceptual process model[3)].

3) From Denmark (G-EPJ, “Basic structure for the Electronic Health Record”, the National Board of Health).

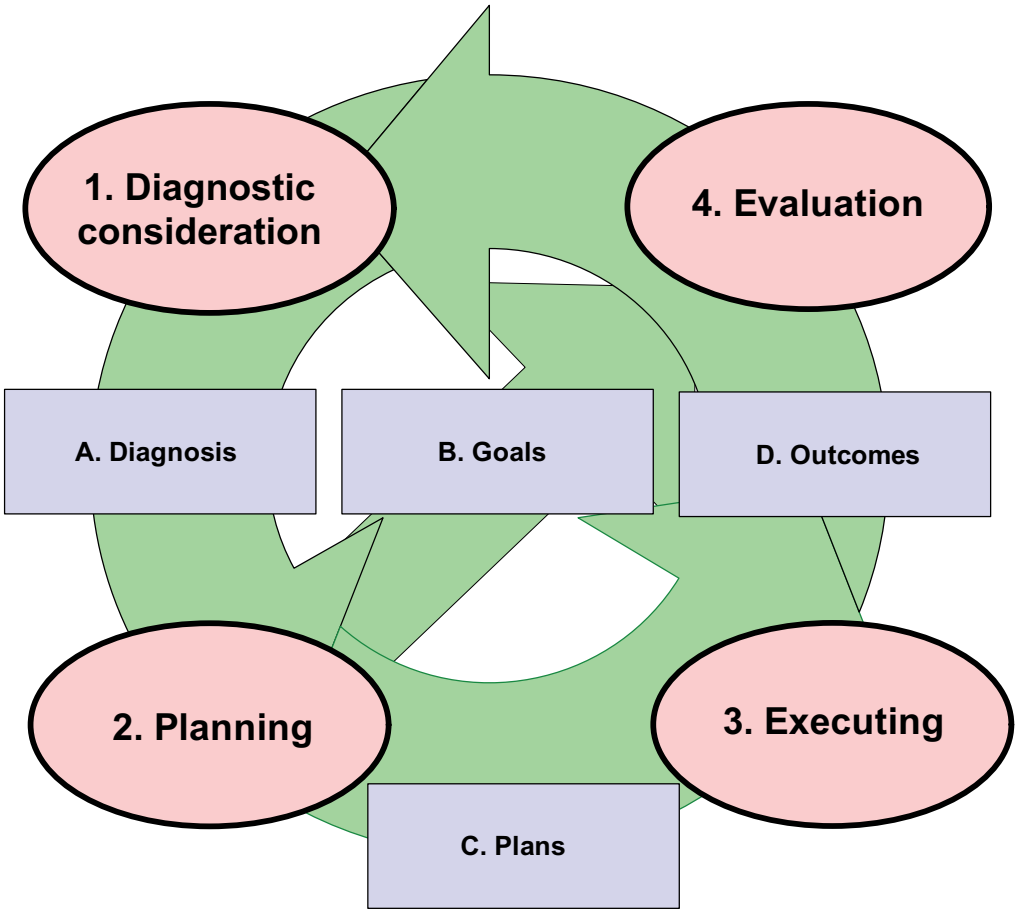

Figure 6 — Clinical process, conceptual model

This model is an example of a problem–solving approach to the clinical process, and an example of what a HISA compliant system and middleware should be able to support. The clinical process is envisaged as consisting of four separate processes that can be executed separately, but that share information. The model is further explained below.

1. Diagnostic consideration

Diagnostic consideration is a process in which facts are collected and analysed in order to understand the problems presented. This process implies that the clinician based on the facts at hand, formulates the problems that are central to the patient. The formulation of the problems is explicated as diagnosis.

A. Diagnosis

Diagnosis is a documentation of how the actual situation is conceived. 'Diagnosis' within the conceptual model is however, defined in a broader sense than in the traditional medical view. This is a necessary consequence of dealing with genuine interprofessional documentation. You can name it 'problem' or 'diagnosis', but basically it should express a professional description of the patients condition, regardless of which professional group the clinician belongs to.

Diagnosis indicates a cause-action relationship for the patient. For example, for a patient with dyspnoea and fear of suffocating, you would say that the fear is a consequence of the dyspnoea. Within the conceptual model, these cause-action relationships are illustrated through outlining the diagnosis in a hierarchy. The diagnosis in the top of the hierarchy indicates the central health conditions. The top diagnosis stipulates separate health threads.

2. Planning
Planning is a process during which activities to be conducted are planned along with the outcome expected. This process incorporates that the clinicians (founded upon their knowledge about the patients problems) outline concrete plans for treatment, care and diagnostics, etc.

Accordingly, through outlining of plans, the clinician can outline operational objectives and thereby formulate the desired outcome.

B. Goals
Goals are a documentation of what outcome is expected. The goals that are documented in this part of the clinical process are not objectives or intentions, but very concrete operational goals. This does not imply that the goals shall be quantitative, just an underlining of that they should be operational.

C. Plans
Plans are the documentation of which interventions are planned. From the interprofessional viewpoint, it could have been named ‘plan’, ‘prescriptions’ or ‘action plan’. This concerns planning intervention in a broad sense.

Plans can include other plans and can therefore have a whole-part relation between them. For example, if you are planning treatment for acute asthma, the treatment can consist of alleviating interventions such as nasal oxygen treatment as well as medical treatment with Salbutamol. Within the conceptual model, these whole-part relationships are illustrated by outlining the plans in a hierarchy.

3. Executing
Executing is a process in which the actual interventions are conducted. This process results in the plans at hand being implemented.

D. Outcomes
Outcomes are a documentation of the actual results following the interventions conducted. In this context, outcome is seen as information about the patients' condition following the interventions in a broad sense.

4. Evaluation
Evaluation is a process in which you compare the expected outcome with the actual results, in order to establish whether the achieved results are acceptable. This process includes that the clinician compares the outcome of the intervention conducted with the operational goals.

The concept of ’clinical evaluation’ includes both a comparison and an assessment. Evaluation within this conceptual model includes merely a comparison between goals and outcomes. The following assessment can be carried out in the process of ‘Diagnostic consideration’ as mentioned in item 1.

This way of perceiving evaluation as distinct comparison makes room for an automated evaluation. Consequently, the clinician is only involved in the evaluation when goals are not achieved.

9.1.4 The operational/clinical and organizational process model perspective

9.1.4.1 Modelling of healthcare

In healthcare, “activity” is a well-established term for everything that is carried out in the care of patients. An agent and an intention can always be identified. Concerning patient-related activities, one agent can be pointed out as responsible for the activity.

The process “care of one individual subject of care” is a deliberate act, and legal rules for responsibility makes it mandatory with a responsible actor/agent. Activities in other processes can influence the process “care of one individual subject of care”, where they are conceived of as events. Events not only affect the core process via the communication process and the management process, but the activities of the core process are influenced directly by events from other processes. Such events may cause aberrations in the result of an activity.

Examples of other processes in healthcare are the patient process, the healthcare authority administration process, resource processes and superior strategic processes.

The core process is called the clinical process in healthcare. The refinement object (term from process modelling, from the Swedish Samba project) is the health condition of the subject of care (synonymous with “patient”, which is used as a short form). The condition can represent a circumstance in the health of the patient, a health issue or health problem (with a state as uninvestigated vs. investigated, treated, assessed, etc.) The activities encompassed are only those which affect the condition or the state of the condition.

The refinement object of the management process in healthcare is the mandate on a general level. A demand for care which has been received by a healthcare provider is a potential mandate for the provider to provide healthcare to the person who is subject to the demand for care. It is a real care mandate when it has been accepted by the healthcare provider, by means of a healthcare commitment. When the mandate has become an effective care mandate, it is the framework for the clinical process, and, within the care mandate, decisions are made on what shall be done and planning of care is carried out. In this process, decisions are made that a certain planned activity actually shall be executed, and evaluation of the results of the activity takes place here. This is a quality assessment. Finally, in the management process, a decision is made to terminate the care mandate and consequently the care process package. Output from the clinical process and the communication process are resources affecting how activities in the management process are executed. Output from the activities in the management process trigger activities in the clinical process and the communication process. (The above processes can take place more or less implicitly/explicitly, according to the organization).

In the communication process, information is the refinement object. Input is the information carried by the demand for care, and that is the refinement object in its original unrefined state. This information will be supplemented with information from other process packages, as well as from the management process. When a decision is made in the management process to request or use external resources, information on these resources are kept in the communication process. The final product, the output, is the termination message, which can take the form of a document (discharge letter, reply to a referral, letter to the subject of care, etc.) or spoken information to the one who has issued the demand for care. In any case, this information is the ultimate refinement of the demand for care and thus the final state of the refinement object.

The activities of the communication process can be triggered by events originating from activities of other process packages, as well as by decisions made in its own process package, in the management process.

The communication process is the shell of the process package. It performs activities that give information to other process packages and to the internal management process, but not to the clinical process. From outside, what is seen of the process package is the communication process.

The three-tiered process model can be used in business modelling of healthcare (Samba, Figure 7).

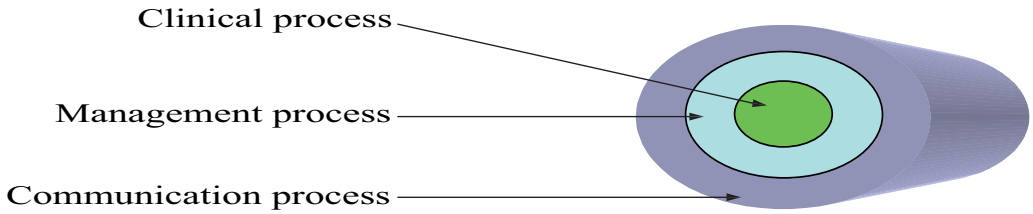

Figure 7 — The Samba three-tiered process model

9.1.4.2 Healthcare process

9.1.4.2.1 General

The following process descriptions in this and the following subclauses are not prescriptive, but describe what is going on in the healthcare domain, explaining/describing the process-oriented nature of healthcare, and how this relates to the services needed from the systems to support the users and the processes.

In the clinical process, the condition of the subject of care is refined. The intention in the process is that the real condition shall improve. But it is only what is conceived that can be registered, and be the basis for how success in the process can be assessed. A condition can be favourable or unfavourable, and the concept condition includes health problems too. Apart from the fact that the conception may give the impression that the condition has changed, also the possibilities to conceive the condition will be changed within the framework of the same refinement object. This happens when the patient is examined, so that the indicated condition is changed from unexamined to examined and then assessed. The real condition is not changed by this, only the perceived condition (the refinement object is actually the perceived condition).

In the management process, the care mandate and its contents is the refinement object. As soon as a demand for care has been noted, there is a preliminary mandate, which will get the full status as a mandate when a healthcare commitment has been stated, and a mutual agreement on care is present between the person who has issued the demand for care and the healthcare provider. The mandate will be the container for decisions in the care process, decided healthcare objectives, care planning, quality assessments and finally a decision that the mandate shall be terminated by revocation of the healthcare commitment.

The communication process has information as the refinement object. Input is information in the demand for care. Statements on decisions, planning and evaluation of activities will be additional information. Information for the documentation of care is provided from this process. The final product is the termination message, which may be a discharge letter, information to the patient, reply to a referral, etc.

The three processes and their refinement objects are depicted in Figure 8.

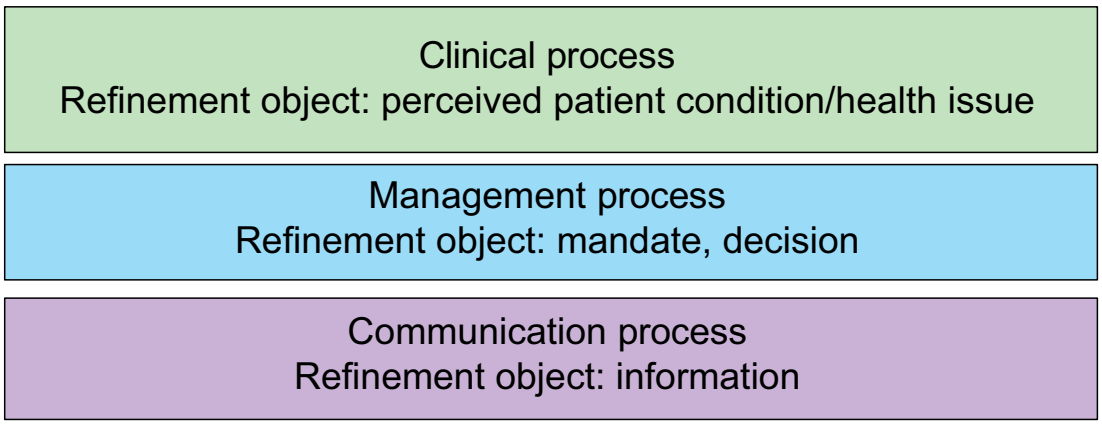

Figure 8 — The refinement objects of the processes

Comparing with G-EPJ, decisions on acts/interventions belong to the management process, with adequate documentation in the communication process. Diagnosis is an outcome of the clinical process, with corresponding documentation in the communication process. The goal is related to the planning for the patient, decided in the management process and documented as needed in the communication process. Thus, the G-EPJ conceptual model and the SAMBA process model constitute complementary ways of modelling healthcare from a process-oriented perspective.

9.1.4.2.2 Notation rules for the three processes

The three processes have been depicted with the clinical process on top, the management process in the middle and the communication process at the bottom.

In each process, the refinement object is traced from activity to activity. The refinement object is depicted as a rectangle. The activity is a solid arrow symbol pointing from input to output. The connection between activity and refinement object is depicted with a thin arrow. This arrow does not represent the workflow but only which object a certain activity yields and which activity will be the next one to influence the refinement object (see Figure 9).

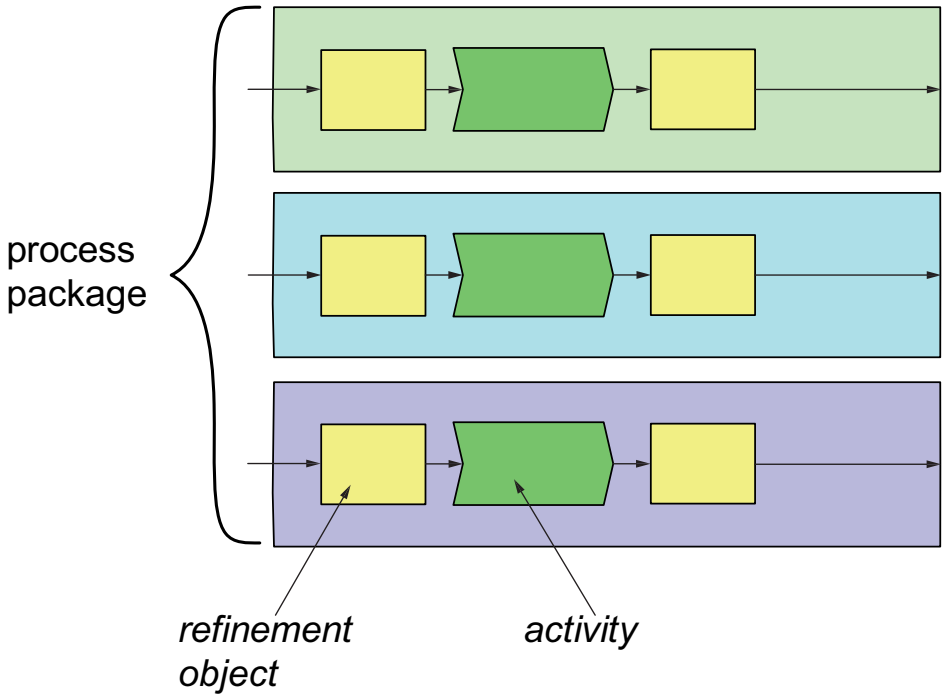

Figure 9 — The symbols of the processes each with its own activity and refinement object

9.1.4.2.3 Care of an individual subject of care

The care of an individual subject of care basically consists of two phases, which are also processes:

— Investigate demand for care. The purpose of this first phase is to investigate the possibility to realize a healthcare commitment based on the information in the demand for care.

— Realize healthcare commitment. The purpose of this second phase is to solve the healthcare problem specified in the healthcare commitment.

9.1.4.2.4 Investigate demand for care

A demand for care is received by the communication process that notes it. The management process decides on evaluating the demand for care. To do this, the type of condition will have to be identified further. Then this type of condition will have to be matched against the service repository, to see if there are services to match it. Based on the list of applicable services, it is decided if this demand for care is accepted, and then a healthcare commitment is created, in agreement with the demander for care. If this fails, it can either be decided to reject the demand for care, or the demand for care can be investigated further, in repeating the process from identifying the type of health issue.

Figure 10 depicts the investigation of the demand for care, and the possible use of healthcare information services provided by the system, to support the process. Healthcare information services are used for registering the demand for care, to possibly access any previous clinical data for the patient, to retrieve the catalogue concerning healthcare services provided and to register the decision regarding healthcare commitment. Four healthcare information services are shown as explicit, meaning that these are shown to be accessed directly, whereas two are shown as implicit, meaning that these are also accessed (directly or indirectly), but this is not shown.

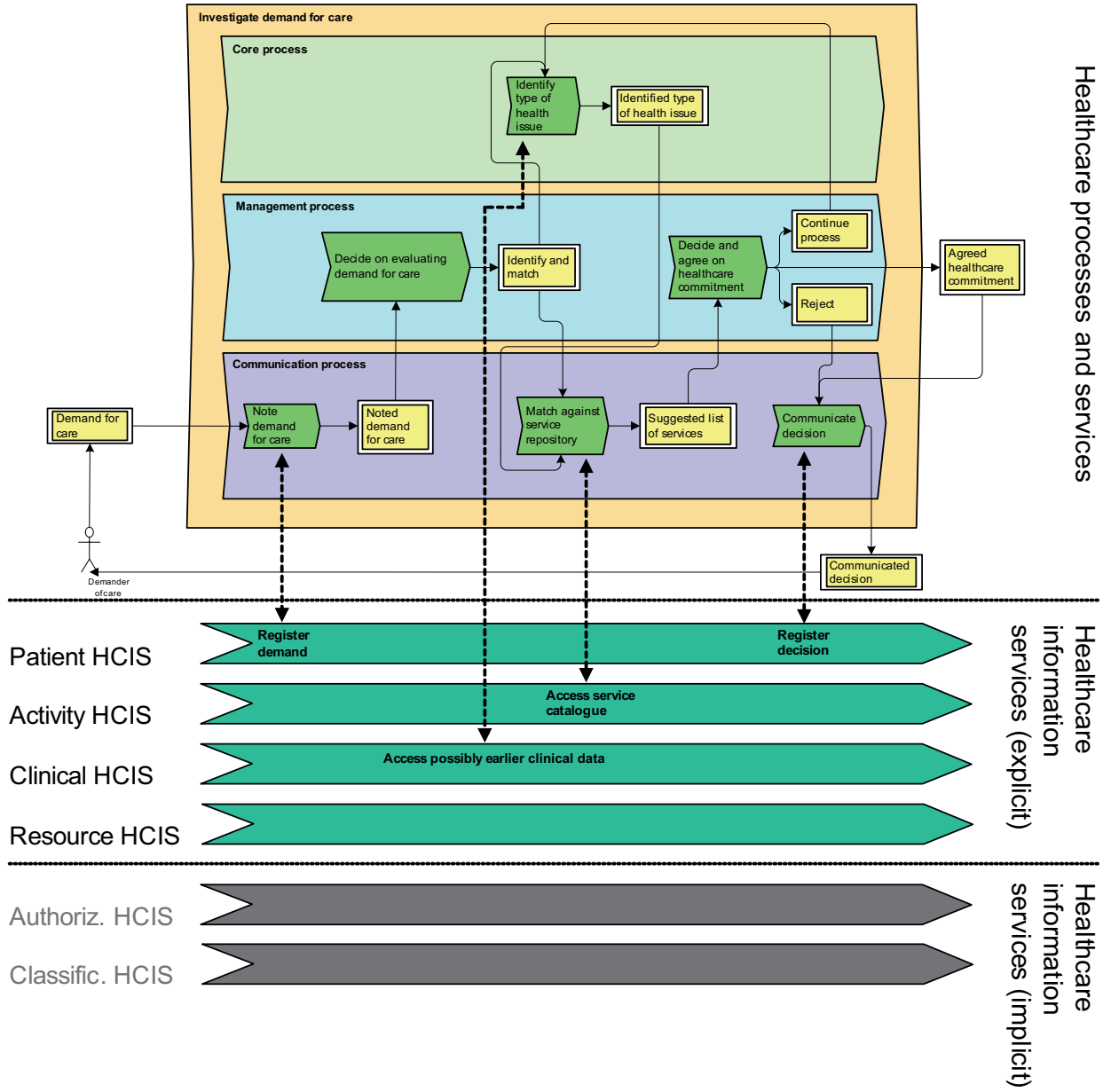

Figure 10 — Investigation of the demand for care, and healthcare information services

9.1.4.2.5 Realize healthcare commitment

The healthcare commitment is registered/recorded in the communication process, to be the basis for the decision on problem and goal formulation. The problems of the patient are formulated in the core process, as well as the goals for the realization of the healthcare commitment. A decision is made to match the problems against the service repository. The match is more detailed, and lists of possible activities are listed, to solve the problems stated and achieve the goals. From the lists, it is decided which activities to plan and execute.

Some of the activities can be carried out in the process, and are thus planned with resources, others must be ordered from an external service provider. The activities performed within the process are carried out in the core process, where results are generated, to be analysed and used for decision regarding continuation. It is decided to continue or terminate the process based on the perceived condition of the patient, from the internal activities/services and from external services. If it is decided to continue, the process is repeated from "Formulate health problems and goals" onward. Even if these are not re-formulated, they must be evaluated in

the light of the new perceived condition. Several iterations can be carried out, in a healthcare flow: Investigate, Decide, Treat, etc.

If it is decided to terminate the process, it must be verified that the patient is taken care of (the process cannot be terminated without agreement on the responsibility for the patient).

Figure 11 depicts the realization of healthcare commitment, and the possible use of healthcare information services provided by the system, to support the process. Healthcare information services are used for registering the healthcare commitment, to access any clinical data for the patient, to retrieve a detailed catalogue concerning healthcare activities provided, to plan, execute and order internal/external activities and the results of these, to access clinical data for evaluation of the patient, and to register decisions. Four healthcare information services are shown as explicit, meaning that these are shown to be accessed directly, whereas two are shown as implicit, meaning that these are also accessed (directly or indirectly), but this is not shown.

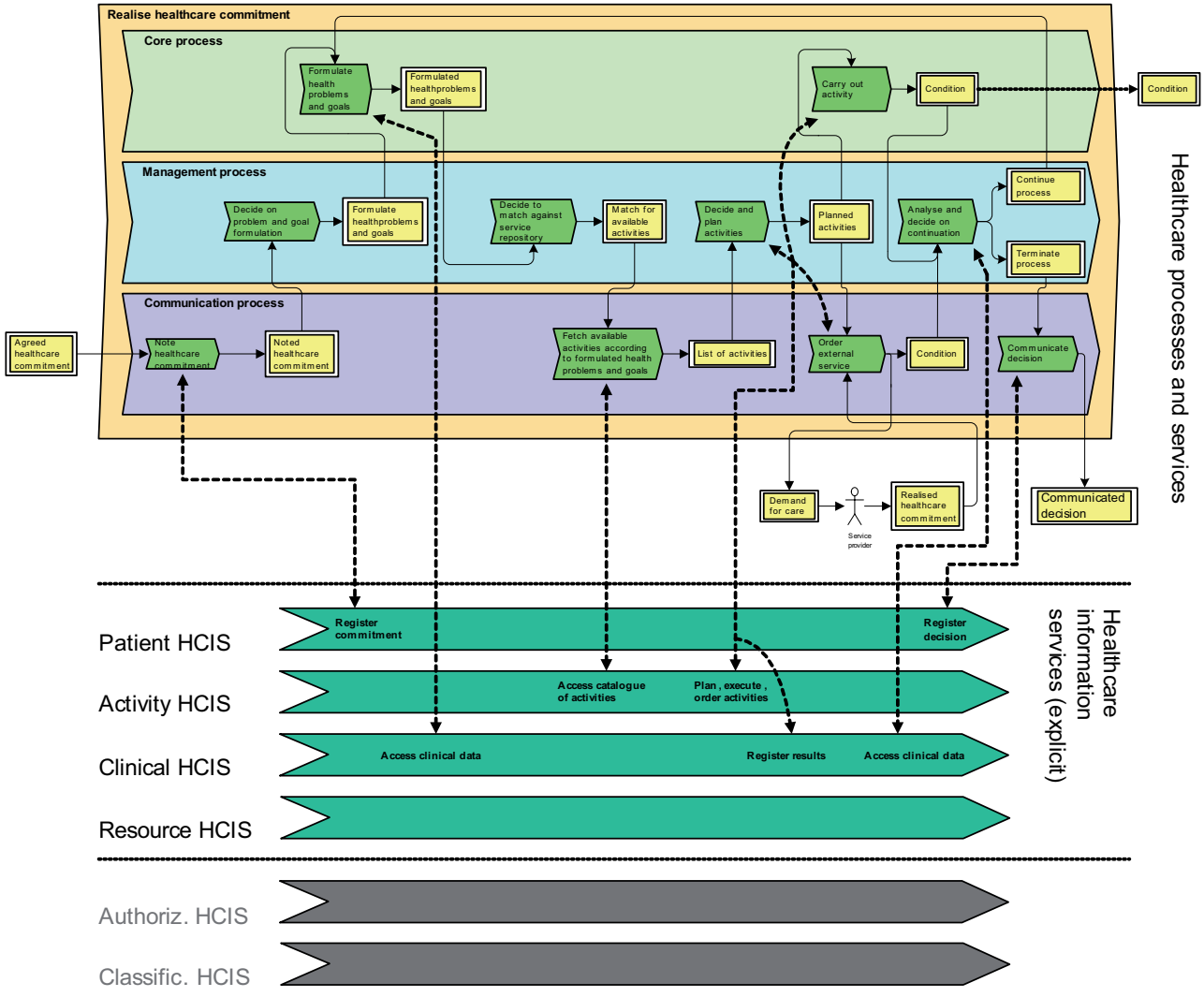

Figure 11 — Realization of healthcare commitment, and healthcare information services

9.1.5 The Healthcare Information Services and their complexity

In the previous subclauses, a number of healthcare activities and services were identified, reflecting different organizational levels and processes.

The information services supporting this can be seen as more or less complex, encompassing smaller or larger parts of potential sets of data-elements and business logic.

It will be up to the actual implementer, to decide the composition and complexity of specific information services for particular usage, especially on the highest level of built-in logic close to the users.

Essentially, the same information sub-services or specializations could be used in many relations and other services. This is also in line with activities that are part of healthcare services, and the further breaking down of activities to its smallest possible atomic parts (deed).

The deed ‘detection of potentials in an ECG device’ could, for example, be supported by a number of more or less complex information services related to the acquisition of ECGs, from the lowest level printing of the signals, to an actual information processing of it (filtering, measurements, displaying, analysis, etc.)

Reflecting the different organizational domain perspectives, few specific assumptions are made regarding the specific data architecture provided by the information services, and flexibility of the information services is required.

In line with the heterogeneous but interrelated nature of the healthcare processes, on, for example, the administrative, clinical and intellectual levels, the information services are required to be context aware. This is also a precondition for the ability of the information services and their information content, to be mappeable and interrelatable across different domain perspectives.

9.2 The fundamental workflows and groups of users’ activities to be supported by the middleware

At a high level of abstraction, the essence of any healthcare environment can be described by the paradigm described in 6.2. This is depicted diagrammatically on an overall level in Figure 12, regarding the main classes/objects and their relation

NOTE The complete HISA information model is provided in ISO 12967-2.

For each workflow and user activity, the following types of requirements are identified, to be supported by the services of the middleware:

— access to, and manipulation of, all elementary information pertaining to the activities of the users’ (e.g. the retrieval of personal data of one patient, the entering of one classification, etc.);

— execution of more complex business transactions, implementing specific business processes and involving multiple types of information (e.g. patient cycle, activities, HCR manipulation, etc.)

NOTE The strategic paradigm (6.2) and the overall diagrammatic representation of it (Figure 12) together with the following subclauses with general requirements, workflows and clusters of users' activities, constitute rationale and basis for the HISA information model in ISO 12967-2 and the HISA services in ISO 12967-3.

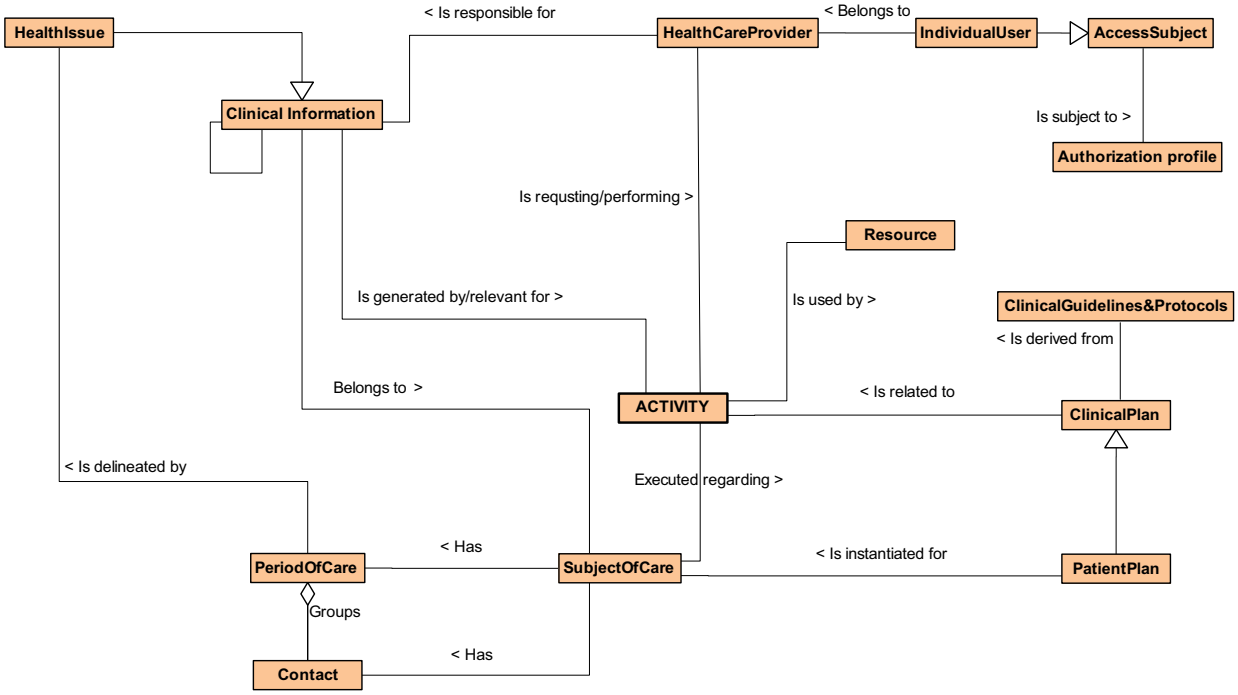

Figure 12 — The overall and main objects/classes and their relation

9.3 General information requirements for all users' activities

9.3.1 Introduction

With respect to the management of information, the following common requirements shall be satisfied by the middleware, in addition to those specific to the individual objects.

Being the enterprise viewpoint, this level is more overall and less detailed. The same requirements are also present in the information viewpoint, in a more complete and detailed manner regarding the information model. The following requirements are stated in the context of the enterprise viewpoint, although fairly close to information model aspects.

9.3.2 Common attributes

All object instances shall be associated with a set of common attributes, which shall identify the following:

— unique, immutable identifier of the object instance;

— time and date of instance creation;

— identification of the agent that created the object instance;

— time and date of last modification of the instance;

— identification of the agent that executed the last intervention on the instance;

— owner of the object (the agent);

— specific authorization information;

— logical deletion of the object.

9.3.3 Extensibility

All objects shall be extensible regarding further attributes, and to the extent that these are not already defined, they should, as a minimum, be definable using the following formal terms:

— description;

— sequence;

— format;

— type;

— size;

— value.

9.3.4 Versioning

The versioning attributes are part of the versioning scheme defined by HISA, and which is further described in the information viewpoint. The versioning attributes are used for the handling of versioning in regard to errors, etc. and not life-cycle management (mentioned in 9.3.6).

All objects shall be possible to version, with attributes identifying the following:

— version identifier;

— version status:

— validity period;

— responsible (agent);

— identification of previous version.

9.3.5 Auditing

In order to meet security related, and rather firm legislative requirements (in the European Union and universally), regarding person- and healthcare-related information, the middleware shall have the ability to audit trail (log) the following events and information:

— date and time of each service call;

— identification of the service calling agent;

— input and output information exchanged with the service calling agent.

9.3.6 Handling of life cycle

Some of the central objects in healthcare have a life cycle (such as period of care, contact, clinical information, demand for care, activity and plan). This means that they usually pass through a number of well defined states, in a reasonably uniform way and sequence.

The life-cycle attributes record the specific life-cycle state, the starting date and time and the responsible agent.

To register the life-cycle states for such objects, life-cycle attributes shall identify the following:

— status;

— date and time of the state change;

— responsible agent.

The use of life cycles supersedes the versioning, which means that the versioning shall not be used for objects with life-cycle characteristics, and that the versioning for these objects is only used for exceptions and errors etc.

9.4 Subject of care workflow

9.4.1 Textual description of requirements

Within the whole healthcare information system, this set of information services is responsible for supporting the applications in the identification of the subject of care (i.e. patients) in the healthcare organization and in the storing and retrieval of those summary personal, clinical and epidemiological data on the individual patients, which are necessary to ensure the consistency of statistical, epidemiological and healthcare analyses carried out throughout different healthcare organizations over the territory.

In the overall scope of the management of basic patient data, a particular role is to be played by the identification of the patient. The presence of a unique identifier for a patient in all the information services related to a healthcare structure, comprising in-patients and ambulatory out-patients, is strongly recommended for any healthcare information system. Other mechanisms may be necessary to permit the correct identification of the patient. With respect to the overall requirements to be supported by the Subject of care healthcare information services, first of all, consideration has to be given to the fact that, although the patient represents the majority of the cases, they can be considered as a sub-group of a more generic class of ”Subject of care”.

The Subject of care is described through several concepts, as he/she undergoes a life cycle starting from his/her registration as a person, (not yet necessarily being a patient), then registering his/her treatment case with all of the describing attributes, up to the registration of the end of the case itself. The treatment may involve several contacts of different types, eventually spanning more than one organization treating the patient. In the following, a brief overview of such a life cycle is described.

The first step involves registering all the available information related to the person regardless of whether or not that person is a patient. The information to be registered is independent of the person’s (future) contacts with the healthcare organization. The person’s information can contain the following types of data:

— personal data (national, regional, or local Id, name, address, birth date, birthplace, etc.);

— other persons in relation with the person to be registered;

— insurance information (guarantor, funding organization, contract terms);

— GP (general practitioner) information;

— demographic information;

— generic health data (allergy information, risk factors, personal antecedents, family antecedents, etc.) collected at registration of the person or already existent data collected by external agents.

The details of information to be managed can vary between different countries and individual healthcare organizations, due to different regulations, attitudes and characteristics of the specific healthcare information services provided. It is beyond the scope of this part of ISO 12967 to define any specific detail for such information which will be specified in individual cases.

From the organizational and clinical points of view, these healthcare information services are able to support the proper management, tracking and follow-up of the contacts had by the patient with the healthcare organization, either as, for example, an in- or out-patient, as well as the clustering of various contacts into groups, e.g. the ”cases” defined for administrative, clinical or epidemiological purposes.

Thus, once a person is registered, it may become necessary to define the date and the type of a future contact with the healthcare institution. The admitting unit/service point can also be specified, when known. The estimated length of the hospital session can be specified. The following are examples of pre-admission-related information that can also be specified:

— referral information (referring agent, unit, referral’s diagnosis, etc.);

— planned resources (location, equipment, staff, materials) to be used with the future contact;

— health data that may be significant for the planned contact (generic health data, exam results, vital signs, other) collected at patient pre-admission or by external agents;

— statistical/demographic/epidemiological data that may be significant for the planned contact.

The foreseen contact (or a not-foreseen contact) may start at a certain time and date, making it necessary to define the exact coordinates of the patient’s stay in the healthcare facility (date, actual type of contact, admitting unit, admission diagnosis) and consider the contact in progress (i.e. ‘actual’ status). If the contact was foreseen, the information entered at preadmission should be updated according to the actual data entered with the admission.

In the following, examples are given of contact-related information that should be entered (or used for updating existing information if pre-admission was performed), at contact registration:

— referral information (referring agent, unit, referral’s diagnosis, etc.);

— planned and actually used resources (location, equipment, staff, materials) to be made available for the future contact;

— health data that may be significant for the planned contact (generic health data, exam results, vital signs, other) collected at patient pre-admission or by external agents.

The responsibility of the patient may change during the treatment, for example when the patient is transferred within the same unit or to another unit. At such transfer, several elements of information should be specified, including the new patient location (unit, service-point), date and time of the transfer, reason for transfer and diagnosis at the transfer. There are also other issues that need to be considered for transfers, such as:

— patient may be on leave for a certain period;

— patient may be temporarily under the responsibility of a different unit/service-point (e.g. the time he/she is undergoing surgery or another activity;

— patient may be discharged, but required to get back to the hospital at a certain date/time.

Finally, when the treatment ends, it becomes necessary to define the ending of the patient’s relation to the healthcare facility, for example, closing the contact and bringing it to ‘completed’ status. Discharge information must be provided (for example, the date and time, diagnosis or reason, etc.). The total cost of the contact may be calculated, and the use of the planned resources can be verified, eventually cancelling the ones not used. The discharging report may be generated and reported to several destinations.

9.4.2 Use-case examples (informative)

9.4.2.1 Initiate period of care

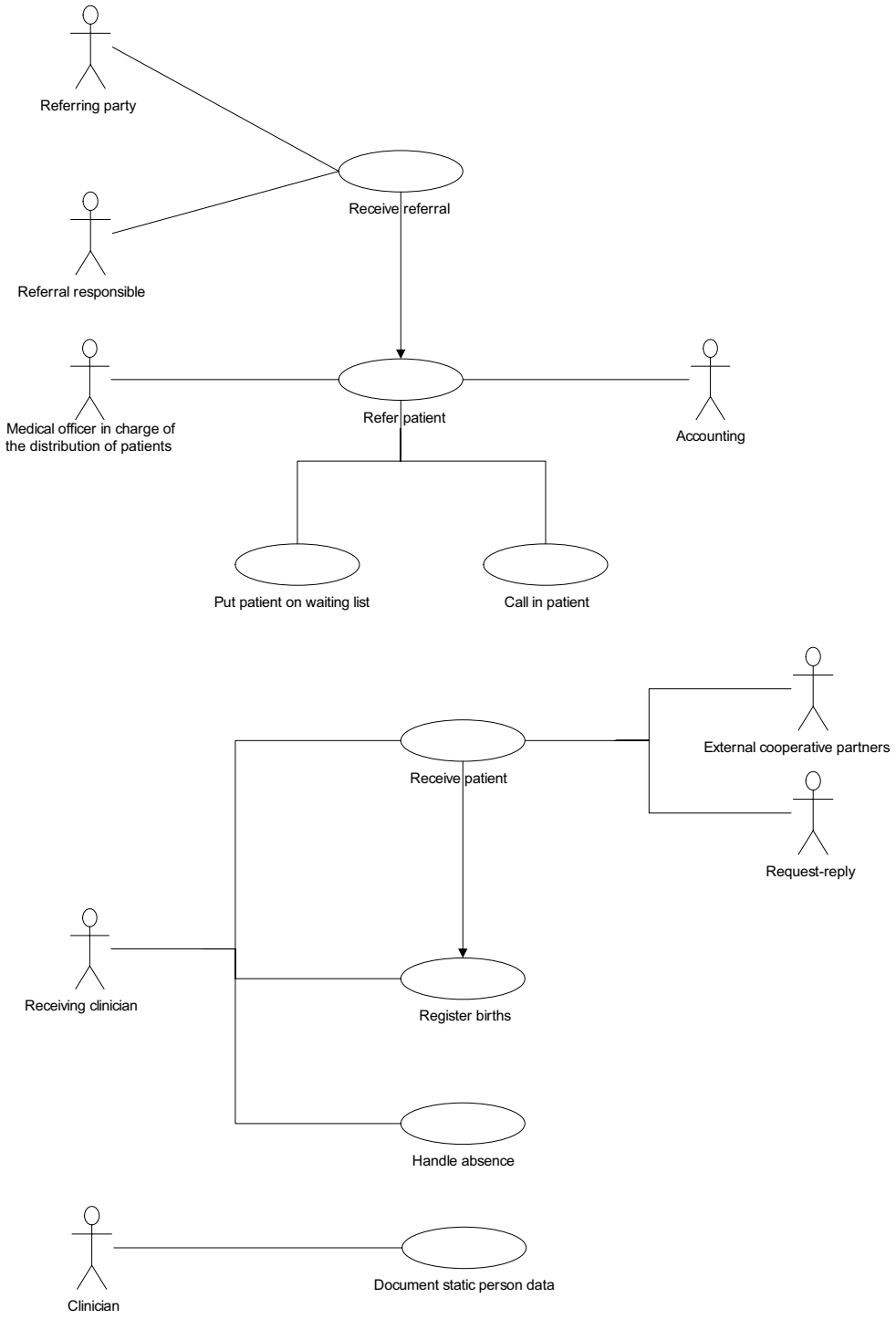

Figure 13 — Initiate period of care: use-case diagram

Use-case name: Receive referral	
Purpose and scope The purpose is to receive and register referrals for the relevant organizational unit, with notification to the unit Referrals are received both centrally and locally	
Event The hospital receives a referral either electronically or on paper.	
Triggering actor The referring party (e.g. own doctor, specialist, other institution, other party (insurance company, Danish Red Cross, etc.)) The referral responsible (clinician or administration with responsibility to receive and register referrals)	
Actions	
1. Create referral (also for acute and emergency admission) 1a. Electronic referral is received 1b. Paper referral is received 1c. The patient is referred by telephone 1d. Notification from other department regarding transferral of responsibility for period of care	
2. Forward referral 2a. The referral is forwarded to the correct organizational unit 2b. The referral is rejected 2c. The referral is returned possibly due to missing information 2d. Request for further information	
3. A receipt is sent to the patient and, in certain cases, the referring party	
Business rules Standards could exist (such as Danish MedCom) regarding content and format of electronic referrals	
End results The referral is registered Receipt for patient and referring party has been sent Medical officer in charge of the distribution of patients has been notified and has taken over the responsibility	

Use-case name: Call in patient	
Purpose and scope For the patient to be called in for the first presence, and receive guidance/information by mail or electronically To respect service measures and treatment guarantees	
Event The referral has been handled and it is decided to call in the patient It is time to call in the patient from the waiting list	
Triggering actor Medical officer in charge of the distribution of patients	
Actions	
1. Create letter to call in the patient, with material 1a. Letter without indication of date	
2. Call in the patient via telephone, and document that the patient has been called in	
Business rules	
End results The patient is called in Documentation that the patient is called in, and how (letter, telephone, electronically) Documentation concerning what material has been send to the patient	

Use-case name: Receive patient	
Purpose and scope This use-case describes the receival of the patient, whether referred or not (acute). The use-case describes work routines which may occur many times in the same period of care. For example: The patient is received in the emergency unit, then the acute receival unit, then a clinical department, then the out-patient clinic For example: The patient arrives the first time in the out-patient clinic, then the clinical department for admission, then the out-patient clinic Depending on an acute or planned period of care, the available data (period of care diagnosis, plan for period of care) could be different when the patient is received	
Event The patient arrives; acute or planned Examples – acute: The patient arrives in the emergency unit (somatic or psychiatric) The patient arrives for the receival with an acute referral from a doctor The patient arrives directly in the unit for acute admission The patient is transferred from another unit/hospital Examples – planned: Referred patient arrives in the out-patient clinic Referred patient arrives in the day hospital Referred patient arrives for admission Referred patient is visited at home (home visit)	
Triggering actor Receiving clinician	
Actions	
Identify patient 1a. The patient cannot be uniquely identified	
The patient arrives (acute) and the period of care diagnosis has to be created	
Read healthcare record	
Register that the patient has arrived 4a. The patient arrives in the emergency unit or in an out-patient clinic 4b. The patient arrives planned in a bed unit 4c. The patient arrives (acute) and has had an accident 4d. The patient is transferred from another unit 4e. The patient is newborn' 4f. The patient is admitted by force	
Allocate a bed for the patient 5a. The patient is located at a unit different from the period of care responsible 5b. Healthy companion	
Contact external cooperative partners (nursing home, home care, general practitioner (GP), etc.)	
Request food and type of food	
Handle patient valuables	
Start initial evaluation of the patient, including updating of person-static data	
Business rules All patients must have a unique identifier. Unconscious patients, foreign patients and other patients where the identity cannot be uniquely defined, are allocated a temporary unique identifier, according to local/national rules	
End results The patient is received, and the patients presence and time of arrival is registered All clinicians involved in the period of care are able to see it	

9.4.2.2 End period of care (diagram only)

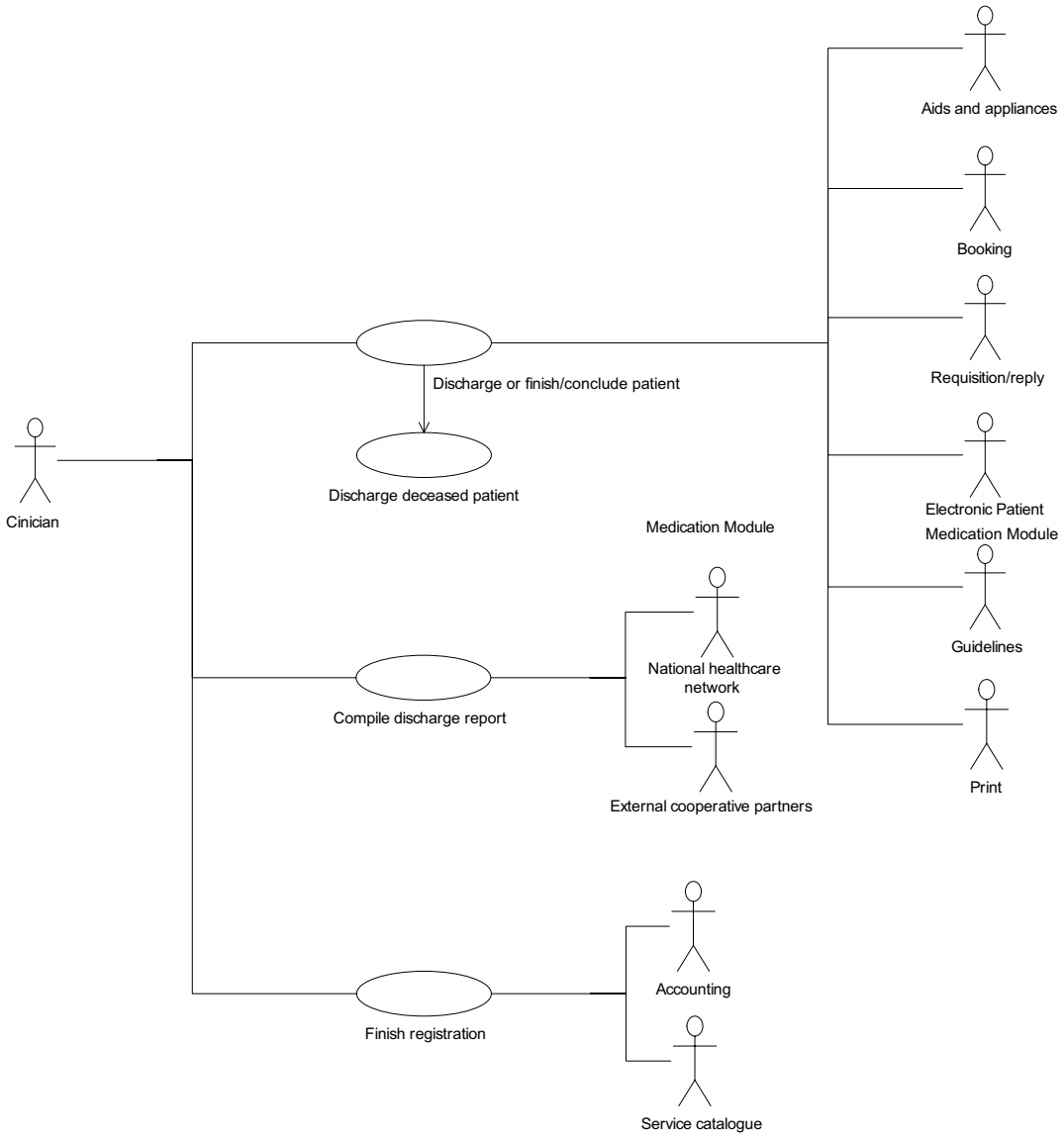

Figure 14 — End period of care: use-case diagram

9.5 Clinical information workflow

9.5.1 Textual specification of requirements

Health data may be either elementary information or aggregations of multiple data on the patient clustered on the basis of different criteria, depending both on the intrinsic characteristics of the clinical information and also on the specific needs of the individual users. It is clear that, even if included in various structured health data, each piece of information must be present only once in the system, to avoid the need for multiple entering and the risk of inconsistencies.

Obviously, such information is of paramount relevance for all healthcare actors in the healthcare organization, both inside the individual centre and throughout the different centres, to provide reliable support in the care process. A set of information services must therefore exist in the architecture of the information system, responsible for providing all applications with a consistent and comprehensive set of mechanisms to define and retrieve the individual pieces of health data.

The clinical healthcare information services cannot be limited solely to the archiving of unstructured data, but must also facilitate the rest of the healthcare information system in the computerized recognition and processing of clinical data in order to satisfy two main needs:

— presentation of data to different types of human users, according to their individual requirements and needs;

— interpretation of individual healthcare data during different processes related to the caring of the patient.

Most parts of the health data available in the healthcare centre represent results of clinical activities carried out by individual healthcare actors. It is stressed that creating direct explicit relationships between health data and activities should represent a major objective of the advanced healthcare information system, providing a major contribution towards two main goals:

— improvement in quality and reliability of the treatment, since healthcare actors may have a more comprehensive and complete understanding of the scenario in which the health characteristic has been collected or generated;

— possibility of monitoring the costs and the quality of the overall organization, by relating individual or complete results with the actual actions being executed.

Nevertheless, not all health data are defined through a formalized activity directly carried out inside the individual centre or relevant enough to be explicitly planned and monitored in the organization. In fact, some health data may be received from external centres as results of external processes, or registered on the basis of daily practice. From the point of view of the information system of the healthcare organization, such health data represent autonomous and self-consistent clinical information, only related to the patient and without any link to the other concepts managed by the information system. As a consequence, an autonomous set of functionalities shall be present in the architecture for managing the workflow of the clinical information, instead of simply integrating such data as additional objects depending on the execution of activities.

9.5.2 Use-case examples (informative)

9.5.2.1 Diagnostic considerations and their documentation

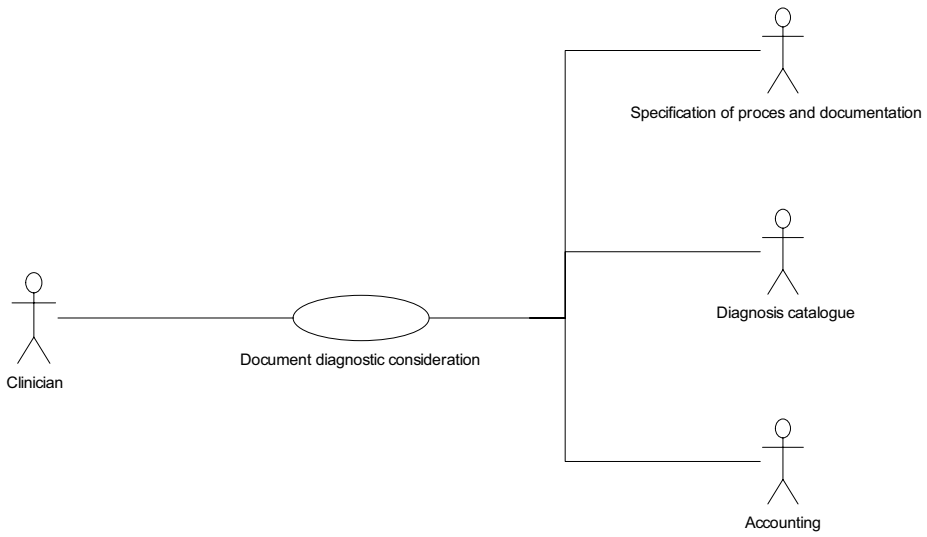

Figure 15 — Document diagnostic consideration

9.5.2.2 The evaluation/comparison of goals and results, regarding the treatment of the patient

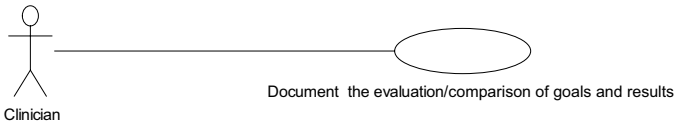

Figure 16 — Document for the evaluation/comparison of goals and results

9.6 Activity management workflow

9.6.1 Textual description of requirements

The structure of a generic healthcare centre may be described in terms of a set of service points, that are organizational elements, i.e. individuals or complete units, which represent functional aggregations, each of them capable of performing certain activities.

With respect to the complete set of requirements of the organization, both the activities, directly or indirectly related to the needs of one patient, and those which are carried out for organizational and administrative purposes have to be considered and supported.

Due to the objective of increasing the level of support to the healthcare actors, as well as of improving the quality of the information services provided and of monitoring the costs, an important requirement of the healthcare organization and, consequently, of the healthcare information system, is the possibility of directly relating each activity to the needs of the individual patient.

The issues related to the management of the activities represent one of the most crucial aspects in the overall healthcare organization. The integration, monitoring and optimization of the overall workflow of the various actors is a primary objective of the healthcare information system, not only for improving the quality of the healthcare information services being provided to the patient, but also with respect to the related organizational, managerial and clinical issues.

The activity healthcare Information services implements complete (and complex) functionalities, providing the applications with a comprehensive support to specific sets of activities relevant to the overall healthcare organization.

For clinical and organizational purposes, protocols can be defined by structuring sequences of elementary or complex activities mutually related, e.g. through a time sequence.

The execution of one activity can make necessary or advisable the preliminary or subsequent execution of a set of complementary activities which cannot be considered as part of the activity; nevertheless being closely connected to it due to clinical, organizational and logistical reasons. Similarly, certain activities and external constraints may interdict the execution of other activities in cases within a certain time frame.

Through the formalization of complex activities, structured as sequences of other elementary activities mutually dependent and related, it is also possible to define complete protocols for clinical and organizational purposes.

The evolution of almost any type of activity performed can be described through a model based on the interactions of several actors during the phases of the activity's life-cycle.

From the moment when one activity is initially thought up to when it is completed, a complex and articulated workflow takes place, potentially involving several actors, in case it is also distributed across different centres and units. A complete life cycle can therefore be modelled for the workflow connected to one activity, comprising a series of events and states through which the activity evolves.

On the basis of decisions made within the healthcare organization, as well as due to request(s) received from outside (e.g. external GPs. etc.), the individual agents may identify a set of activities to be actually performed either inside the same unit or by different agents of the organization. An actual activity is the instantiation of a certain type of activity, to be executed by one individual unit for one specific situation, upon request of one specific requester.

According to the general classification criteria, acts may not only refer to individual patients but they may also relate to any kind of activities that are executed in the organization of the healthcare centre

According to the information provided by the classification data, both the units that may execute the envisaged information services and the list of the relevant complementary actions may be identified. Through this information, a set of actual activities to be performed is detailed.

During its life cycle, each individual act is always related at one time to one unit (and service point) of the organization, which is considered "in charge" of the act. The unit (and service point) in charge of the act identifies, in that particular moment, who is actually responsible and allowed to perform some actions and, in some cases, evolving the act to a different status. Usually, either the requesting or the providing unit is in charge of the act. In some cases, other units of the organization may also play an active role.

The typical life-cycle of one activity may be schematized as follows:

— on the basis of local needs as well as due to requests received from outside, one actor may decide to request a set of activities from other actors of the healthcare organizations both inside and outside the centre;

— for each group of homogeneous activities, a formal requisition may be sent by the requester to the service point which is supposed to deliver the information services. The request details the list of the information services which are requested, specifies the reasons for the requested service and includes other possible administrative and clinical information, depending on the organization and type of activities requested;

— when the provider receives the request, a communication is sent to the requesters, informing them of the acceptance of the request and providing, if necessary, other information;

— for several reasons, it may happen that all or some of activities in the request, even if already accepted, cannot be performed by the provider, who decides to forward the whole or part of the request to a different unit, informing the original requester of the situation; such a process may be repeated several times, especially in the case of very complex activities;

— then the individual activity is scheduled, defining the real date and time when it is supposed to be executed; such information is communicated to the requester in case it is integrated with other information;

— even if the activities are already scheduled in the delivering service point, some modifications may be decided upon either by the requester or by the service provider, concerning the actual date and time of execution; such modifications are usually negotiated between the actors involved on the basis of their mutual requirements;

— at a certain moment, usually but not necessarily according to the date initially scheduled, a scheduled activity is performed by the delivering actor;

— execution of the activity may last a certain time; during which period some intermediate communications may be interchanged between the provider and the original requester;

— additional activities, even if they are not initially requested, may be performed by the provider, for various reasons. Such activities always refer to the original request;

— when all activities related to the delivery of the requested service by the providing unit have been completed and a final report with the consolidated results of the activity has been finalized, the initial request can be considered to be completed and a formal communication is sent to the requester who formally acknowledges receipt of it.

The different states of one act may be summarized in Table 1.

Table 1

Foreseen	The activity to be carried out has been identified by the requestor, but a formal request or planning has not been issued yet.
Requested	A formal request has been sent to the provider supposed to deliver the service(s)
Accepted	The providing unit has formally accepted to provide the service.
Booked	The actual activities to be executed have been identified and a date, shift and time for execution has been agreed between the involved agents (i.e. requestor, provider and other involved units).
Planned	The act has been assigned to one (set of) Service Point(s), which will be in charge of its execution.
Ready	All preliminary activities have been completed and the execution of the act may actually start
In progress	The execution of the act has actually started.
Completed	The provider has completed the actual execution of the act.
Reported	The provider has delivered the final report on the act.
Terminated	The final report has been received and accepted by the original requester.

In addition to these basic (almost sequential) moments, the evolution of the act may also pass through the states In Table 2.

Table 2

Forwarded	The request of delivering the service has been transferred by the initially envisaged provider to a different provider.
Suspended	The processing of the act (at any moment of its life-cycle) has been temporary interrupted due to various reasons [a]
Annulled: Cancelled Rejected	One act may be annulled either by the requestor (that cancels the request) or by the envisaged provider (that may reject the request received)
Substituted	The act has been substituted with another one
[a] Typically some more information is necessary to make decisions on further steps to be carried out.	

It is emphasized that this formal and complete sequence of states is not always applied in reality, since various phases may be skipped under certain contingencies.

Upon execution of each activity, various results may be generated, comprising coded data, textual information and other types of data. This information may be structured according to different criteria, depending on the characteristics of the activities and the specific actor's way of working. Depending on the type of activity which is being executed, such results may represent health data of the patient, or just data of another type to be communicated in the healthcare organization.

When executing one activity, a set of resources is used in terms of equipment including the time of staff, materials and consumables.

On the basis of these considerations, it is clear how a set of information services supporting the applications in the management of the life-cycle of the activities represents a fundamental element of the middleware, necessary both with respect to the integration of different applications and to the point of view of the integrity of the data relevant for the healthcare organization as a whole. In fact, such healthcare information services will

— provide a common set of mechanisms for the functional and information interactions of the applications during the various phases of the life-cycle of the activities, from the initial request to the final reporting, and

— provide a common repository, accessible to all other interested modules, containing information on each activity being performed in the organization and relevant to more than one application, representing a vital basis for supporting both the clinical and organizational requirements of the individual users and the calculation of costs and quality of information services.

It is stressed that the management of the execution of the phases of the activities will not be the responsibility of such healthcare information services. This will be carried out by the individual applications, through ways and interfacing mechanisms optimized with respect to the specific user needs being supported.

9.6.2 Use-case examples (informative)

This suclause deals with the use-case regarding execution of activities and documentation of results.

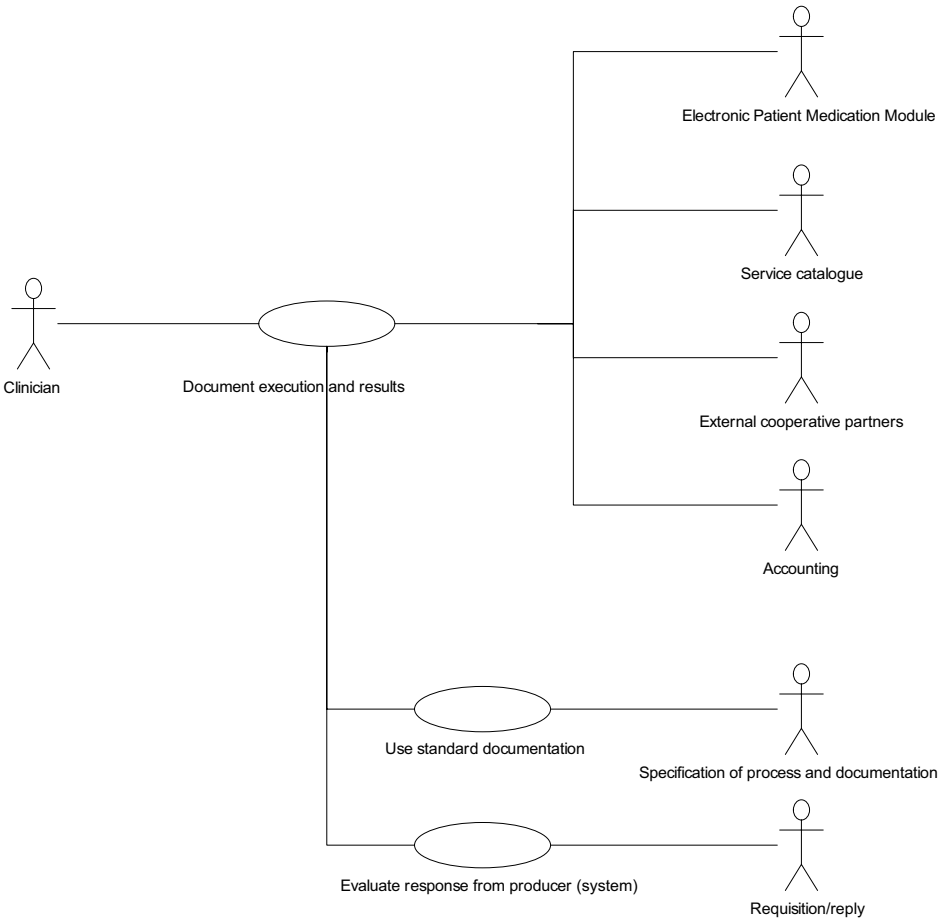

Figure 17 — Use-case diagram regarding execution of activities and documentation of results

Use-case name: Document execution and results	
Purpose and scope This use-case describes tasks regarding execution and documentation of planned and non-planned activities. In regard to planned activities (activities created in the patients plan), the clinician should be supported in carrying them out. If an activity has not been planned, the clinician should be able to create and document the execution of the activity in the same workflow. The documentation can be ad hoc (e.g. automatic transferral of results from the laboratory system) or post hoc (a lot has been done, which is documented subsequently) The content and scope of the documentation depends on the activity, and, in some cases, it will be enough to document that the activity is executed, while other activities lead to a result (product). The content of the activity result depends on the activity type, and the content of the activity result can be, for example, numbers, curves/diagrams, images, narrative text. The work tasks in this use-case are described using some result archetypes. A result archetype is concerned with a collection of activity results, where the necessary functionality to document the activity result, in principle, is the same. The clinician needs, for example, the same functionality for the activity results 'recorded patient history' and 'description of operation', such as word processing functionality, for which reason both activity results belong to the result archetype 'narrative documentation of activity result'. The optimal support for the work flow/routine 'documentation of execution and results, is achieved through pre-defined schemas and templates. These are in the following named 'standard documentations' to visualize the far more advanced functionality than paper based schemas. The creation and design of standard documentations is handled by the '*Module for process and documentation specification'*.	
Event Execution and documentation of one or more planned activities Execution and documentation of one or more acute activities Examples: The patient is operated The patient has blood pressure and temperature measured The patient has a diagnostic examination The patient is rehabilitated The patient gets help with personal hygiene The patient has an ECG made The patient attends prenatal control The patient has an objective examination	
Triggering actor Clinician	
Actions	
Check that consent has been given	
Select an activity to be executed/documented. 2a. Same activity should be executed for several patients 2b. Execute several activities for the same patient 2c. The activity is not created	
Document the execution of an activity	
Document the execution and result using standard documentation	
Document the activity result in narrative text	
Document activity results which lead to a diagnosis	
Document numerical measurement results	
Document activity results using a scale 8a. Binominal scale 8b. Nominal scale 8c. Rank scale	
Document the activity result on a graphical scale	
Document the activity result on a visual analog scale	
Document the activity result by digital images or video	
Document the activity result by digital drawing	

Document the activity result by digital sound
Document activity results which are available on paper
Compare the activity results with similar results in the patients record 15a. Show earlier activity results of the same type 15b. Show operational goal for the activity
Communicate matters regarding unfinished activity results and execution notes 16a. The activity has been executed, but not yet documented 16b. The result is a draft
Evaluate the activity result from a producer (system)
Document information which is not a result of an activity
Document an ongoing activity which is supposed to pause (typically activities regarding medication)
Document an aborted/interrupted activity
Use guidelines for documentation of the execution note or activity result 21a. Document handed out for patient instruction
Document the same execution note or activity result for several patients
Handle accounting-related matters regarding activities
Print result 24a. Send the result electronically
Business rules
End results The activities are executed and documented The activity is aborted/interrupted and the reason is documented.

9.7 Resources management activities/Textual description of requirements

Healthcare resources represent the fundamental elements that are necessary to enable an organization to work. Various types of resources may be identified, such as personnel (clinical, technical, administrative), materials including drugs, equipment and even the individual locations where the work is performed.

This means that, in order to support the needs of the various types of users properly, all applications need to take into account the characteristics and availability of the resources which are supposed to be used in each individual case.

Furthermore, it is important to recognize that most resources represent a common heritage for the whole organization, usable or necessary for supporting the needs of different areas and users. An optimized management of individual resources, taking into account both local and more general needs, will largely contribute to improving both the quality and the costs of the healthcare information services being provided.

In addition, it must be remembered that resources are not only relevant for the activities of the clinical users, but also represent a major concern for a number of other functional areas of the healthcare organization including a warehouse, a pharmacy, accounting and assets, technical support and maintenance and personnel management.

As a consequence, common mechanisms are necessary in the information system, to allow the definition and retrieval of information on the resources actually available in the organization, as well as on the criteria and rules according to which each resource can or must be involved in executing or contributing to certain work.

9.8 Management activities for users and authorizations/Textual description of requirements

The definition and control of the authorization of individual users in the execution of various activities and in the access to different information represents a major concern in the healthcare environment.

In fact, besides the need for supporting the diversification of roles and responsibilities which is typical of any type of large organization, additional critical aspects can be identified in the healthcare scenario due to the particular type of information which is managed, implying also ethical and legal aspects.

Furthermore, major differences still exist between different countries and even between individual healthcare centres concerning the actual responsibilities and roles of different clinical professionals who have the patient in their care.

On the basis of such considerations, two fundamental and complementary needs can be identified for the information system:

— security of the managed data;

— control and monitoring of the actual authorization for individual users executing certain activities on the system.

Security relates to the criteria and mechanisms according to which data must be managed, e.g. stored, transmitted and manipulated, by the overall system to ensure an adequate level of reliability and protection. Such aspects may also imply, amongst others, the enciphering of the information and the utilization of specific devices to ensure the correct identification of individuals. As a consequence, security represents a characteristic of the system closely dependent on and related to the technological features. Furthermore, implications and dependencies may also be identified, with standards and recommendations being defined by proper committees of the healthcare and information technology community. As a consequence, security is outside the scope of this part of ISO 12967 and of this set of information services of the standard.

Apart from the need for ensuring the intrinsic security of the data, another major requirement can be identified in the need of the individual healthcare centre to define criteria and rules according to which the individual users may be authorized to access the system and perform the various activities, according to their specific role and responsibility in the organization. Such criteria vary throughout the different centres, for organizational, cultural and practical reasons, and may also change frequently.

In fact, different responsibilities can be identified in the healthcare organization regarding the role and activities of the users. Moreover, moving from country to country or from one healthcare centre to another, different types or levels of authorization may be applied to similar types of users, both for execution of particular functions and for access to the information.

The middleware shall provide common mechanisms supporting this specific need, by providing:

— comprehensive and consistent repository where those responsible in the organization may define the rules according to which the different users may execute the functions provided by the system;

— standard mechanism in terms of information services available and information managed, according to which the rest of the system may check whether one user is allowed to perform the activities they are requesting.

With respect to the requirements to be satisfied by the Authorization Information services it should be stressed again that the functionalities provided by these Information services are completely independent of any kind of complementary security mechanisms which may be defined and implemented in the system to secure and protect the individual data.

Irrespective of the technological aspects, the entire healthcare information system consists of a number of components, which are either applications or services. From its internal perspective, each component interacts with various external agents, which may be either individual users or other components.

Each component may be described in terms of a set of controlled functionalities, whose invocation and manipulation by external agents is subject to specific authorizations.

For each component, a set of authorization profiles are defined, usually reflecting the various jobs and responsibilities in the organizational area where the system is operating. Each authorization profile may operate with a set of controlled functionalities, according to one set of conditions, which describe its authorization in terms of a set of information, such as:

— working ways which define whether the profile is allowed to access that element by adding new data or reading, updating, or deleting existing data;

— time frame which permits the specification of the temporal limits of the authorization, through a start and end time every day;

— days of the week which specify the individual days of the week when the agent is allowed to interact with the object;

— workstations, which specify a list of workstations or nodes of the information system from which the agent is allowed to interact with the object.

Subject to specific individual approval, defined in the specific conditions, any generic agent of one profile may be authorized to define agents of the same profile, as well as of other profiles of the system.

Each agent of the healthcare information system can be characterized by a name, a unique public identifier, e.g. a code, and some mechanisms for ensuring its correct identification. To access a component, the agent must be a member of one authorization profile of that component. Such membership is granted by another individual agent, and is valid in a specific time period only, i.e. between a starting and an expiration date.

Exceptions may be defined, in terms of extensions or limitations of the authorization of one individual agent, with respect to the standard authorizations defined for its profile. Also, such exceptions must be defined by one individual agent and are described through a set of conditions

9.9 Classifications, coding and dictionaries management activities/Textual description of requirements

In order to provide integrated support of user activities across the entire healthcare enterprise, not only the operational information related to the daily routine, codes and classifications must be integrated in one common enterprise information model. Through common facilities, users also need to manage (i.e. to define, to retrieve and to manipulate), in an integrated environment:

— multiple semantic types and classifications usable for the various concepts of the information system;

— common vocabularies covering the set of terms that applications need and employ to describe the application domain;

— dependencies and rules which may exist between different mutually related concepts, as well as between different individual instances on the basis of specific values of their attributes;

— rules indicating the way in which vocabulary items may be instantiated;

— mapping between the element of the common, integrated, information model and the structure of messages and views requested by specific healthcare data-architecture and communication standards (e.g. RIM, CONTSYS and GPICS), adopted to support interactions with other systems and/or specific users activities in the individual sectors of the organization.

Such requirements not only relate to the individual workflows and users' activities, but also span multiple areas from the clinical, organizational and managerial points of view.

As a consequence, two sets of requirements shall be supported by the middleware:

— for each workflow and cluster of users' activities, the management of the dictionaries, classifications and rules adopted by the enterprise for that specific process;

— at a global, enterprise level, the management of dependencies and relationships among different concepts for clinical, organizational and managerial purposes also spanning multiple areas and the mapping with other specific standards.

On the basis of the fundamental concepts relevant to the workflows and clusters of users' activities identified in 9.4 to 9.8, the following semantic types and classes are therefore identified:

— Class of Contact

— Class of Period Of Care

— Class of Clinical Information

— Class of Activity

— Class of Clinical Plan

— Class of Resource

— Class of Healthcare Provider

— Class of Authorization Profile

Additional semantic types may be necessary in the individual scenarios, according to the local requirements and extensions.

The middleware, therefore, shall provide mechanisms supporting the users in the definition and management of classifications, codes, dictionaries and relationships among such concepts.

It is emphasized that this represents an additional requirement with respect to the need of managing the specific codes, classifications and rules pertaining to the users' activities described in 9.4 to 9.8. As a consequence, the presence of the objects identified in this paragraph shall not imply that the functionalities provided by the middleware for supporting the users' activities specified in 9.4 to 9.8 will be limited to the sole management of the daily, operational data. Such a limiting approach would create critical dependencies between the various classes, with the negative consequence of reducing the modularity of the whole system, and limiting the possibility of implementing or evolving it gradually through the integration of heterogeneous software modules which may already exist or be provided by different suppliers.

On the contrary, this part of ISO 12967 identifies a modular set of self-consistent services, each of them capable of providing a consistent and, as far as possible, complete support to a certain set of user needs. As a consequence, each group of services supporting the individual workflows or clusters of activities shall also be responsible for including services allowing the management of the full set of information related to its scope, (i.e. both classifications and actual daily data), without intrinsic dependencies from other components.

As a consequence, each group of services may exist in one real information system even without the concurrent presence of the others. Should a group of classifications, coding and dictionary management services be present in the information system, the other healthcare information services conformant to it will refer to its service for retrieving a controlled and integrated set of classification criteria and rules, useful for improving the level of support that they are able to provide autonomously to the users as shown in Figure 18.

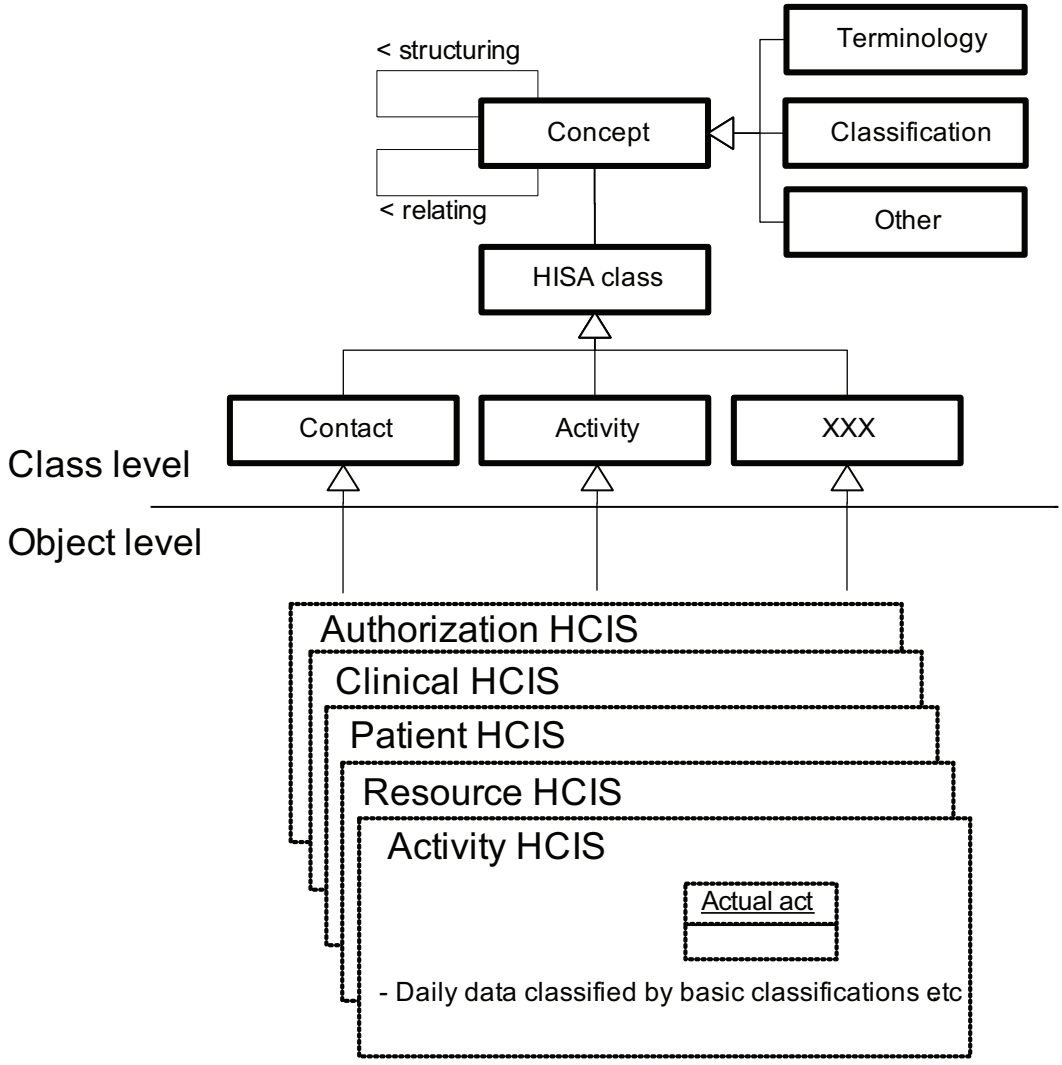

Figure 18 — The role of the classifications, coding and dictionaries management information services with respect to the other Information services

Annex A
(informative)

Highlights of Open Distributed Processing (ODP)

This part of ISO 12967 formalizes the architecture by using the methodology of ISO/IEC 10746 (all parts) Information technology — Open Distributed Processing.

The objective of ODP standardization is the development of standards that allow the benefits of distributing information processing services to be realized in an environment of heterogeneous IT resources and multiple organizational domains. These standards address constraints on system specification and the provision of a system infrastructure that accommodate difficulties inherent in the design and programming of distributed systems.

Distributed systems are important because there is a growing need to interconnect information processing systems. This need arises because of organizational trends such as downsizing, which demand the exchange of information both between groups within an organization and between cooperating organizations. Advances in technology are making it possible to respond to these trends by giving increasing importance to information service networks and personal workstations, and by permitting the construction of applications distributed across large configurations of interconnected systems.

In order both to manage system distribution and to exploit it (e.g. use the potential for availability, performance, dependability and cost optimization), organizations must deal with a number of key characteristics of system distribution:

— **Remoteness**: Components of a distributed system may be spread across space; interactions may be either local or remote.

— **Concurrency**: Any component of a distributed system can execute in parallel with any other components.

— **Lack of global state**: The global state of a distributed system cannot be precisely determined.

— **Partial failures**: Any component of a distributed system may fail independently of any other components.

— **Asynchrony**: Communication and processing activities are not driven by a single global clock. Related changes in a distributed system cannot be assumed to take place at a single instant.

— **Heterogeneity**: There is no guarantee that components of a distributed system are built using the same technology and the set of various technologies will certainly change over time. Heterogeneity appears in many places: hardware, operating systems, communication networks and protocols, programming languages, applications, etc.

— **Autonomy**: A distributed system can be spread over a number of autonomous management or control authorities, with no single point of control. The degree of autonomy specifies the extent to which processing resources and associated devices (printers, storage devices, graphical displays, audio devices, etc.) are under the control of separate organizational entities.

— **Evolution**: During its working life, a distributed system generally has to face many changes which are motivated by technical progress enabling better performance at a better price, by strategic decisions about new goals, and by new types of applications.

— **Mobility**: The sources of information, processing nodes and users may be physically mobile. Programs and data may also be moved between nodes, for example, in order to cope with physical mobility or to optimize performance.

Building such systems is not easy. It requires architecture and, because a single engineering solution will not meet all requirements, it must be a flexible architecture. Moreover, since a single vendor will not have all of the answers, it is essential that the architecture, and any functions necessary to implement the architecture, be defined in a set of standards, so that multiple vendors can collaborate in the provision of distributed systems. Such standards will enable systems to be built with the following characteristics.

— They are **open** – Providing both portability (execution of components on different processing nodes without modification) and interworking (meaningful interactions between components, possibly residing in different systems).

— They are **integrated** – Incorporating various systems and resources into a whole without costly ad-hoc developments. This may involve systems with different architectures, and different resources with different performance. Integration helps to deal with heterogeneity.

— They are **flexible** – Capable both of evolving and of accommodating the existence and continued operation of legacy systems. An open distributed system should be capable of facing run-time changes, for example, it should be capable of being dynamically reconfigured to accommodate changing circumstances. Flexibility helps to deal with mobility

— They are **modular** – Allowing parts of a system to be autonomous, but interrelated. Modularity is the basis for flexibility.

— They can be **federated** – Allowing a system to be combined with systems from different administrative or technical domains to achieve a single objective.

— They are **manageable** – Allowing the resources of a system to be monitored, controlled and managed in order to support configuration, QOS and accounting policies.

— They meet **quality of service** needs – Covering, for example, provision of timeliness, availability and reliability in the context of remote resources and interactions, together with provision of fault tolerance that allows the remainder of a distributed system to continue to operate in the event of failure of some part. Provision of fault tolerance (and of dependability in general) is necessary within large distributed systems where it is unlikely that all parts of the system will ever be operational simultaneously.

— They are **secure** – Ensuring that system facilities and data are protected against unauthorized access. Security requirements are made more difficult to meet by remoteness of interactions, and mobility of parts of the system and of the system users.

— They offer **transparency** – Masking from applications the details and the differences in mechanisms used to overcome problems caused by distribution. This is a central requirement arising from the need to facilitate the construction of distributed applications. Aspects of distribution which should be masked (totally or partially) include: heterogeneity of supporting software and hardware, location and mobility of components, and mechanisms to achieve the required level for QOS in the face of failures (e.g. replication, migration, checkpointing, etc.).

ODP standardization has four fundamental elements:

— object modelling approach to system specification;

— specification of a system in terms of separate but interrelated viewpoint specifications;

— definition of a system infrastructure providing distribution transparencies for system applications;

— framework for assessing system conformance.

Object modelling represents a fundamental qualifying aspect of the whole ODP approach. It provides a formalization of well-established design practices of abstraction and encapsulation. Abstraction allows the description of system functionality to be separated from details of system implementation. Encapsulation

allows the hiding of heterogeneity, the localization of failure, the implementation of security and the hiding of the mechanisms of service provision from the service user.

The object modelling concepts cover the following.

— Basic modelling concepts – Providing rigorous definitions of a minimum set of concepts (action, object. interaction and interface) that form the basis for ODP system descriptions and are applicable in all viewpoints.

— Specification concepts – Addressing notions such as type and class that are necessary for reasoning about specifications and the relations between specifications, provide general tools for design, and establish requirements on specification languages.

— Structuring concepts – Building on the basic modelling concepts and the specification concepts to address recurrent structures in distributed systems, and cover such concerns as policy, naming, behaviour, dependability and communication.

Annex B
(informative)

Rationale for the federative structure of the Health Informatics Service Architecture

The rationale underlying the HISA standard is based on the organizational aspects of the healthcare enterprises, combined with the scenario of the IT solutions for the healthcare market.

At a high level of abstraction, any healthcare organization can be described by means of a federative model, as a set of organizational units, mutually interacting for the effective delivery of services. Each organizational unit of the healthcare organization has a certain level of autonomy and independence, in terms of information managed and activities supported, which can vary according to the specific organizational, clinical and logistical characteristics of the individual centre and, even within the same centre, according to the specific aspects of the individual units.

Such organizational characteristics should be reflected in, and supported by, the characteristics of the information system, with regard to the information managed and the functionalities provided.

A basic ”conceptual architectural framework” capable of meeting such combined requirements of independence and collaboration can be structured in three overall layers as follows.

1. Application layer

Relates to the functioning of individual organizational units or specialties, and consists of a set of autonomous components individually supporting the specific requirements and functionalities in the various units of the organizations.

2. Middleware layer

Relates to the functioning of the healthcare organization as a whole, and is responsible for supporting the functional and informational interchange of the individual applications, and of the definition and management of information and procedures of paramount relevance to the overall healthcare organization.

3. Technological layer (bitways)

Relates to the basic technological platform for the physical connection and interaction of all components of the system i.e. both applications and common services.

Figure B.1 shows how such layers of the architecture are related to the levels and needs of the organization.

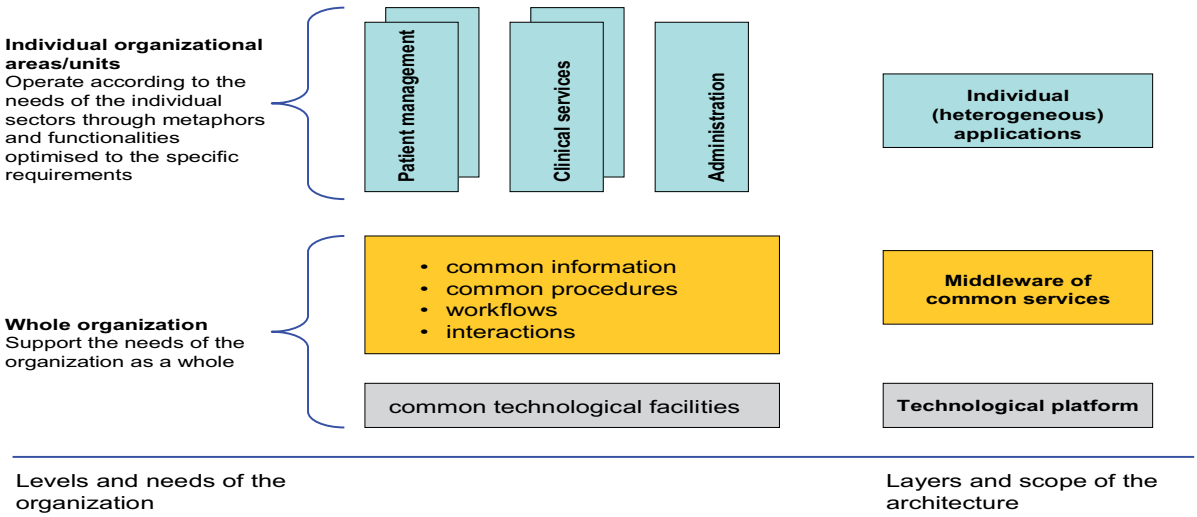

Figure B.1 — Correspondence between the levels of the organization and the layers of the conceptual architectural framework in which functional areas or units represent examples

The application layer can be further divided into the following layers.

1. Presentation layer

Relating to the presentation aspects

2. Application logic

Relating to the aspects of preparing the output of the information services for its presentation to the user of the specific application.

According to the evolution of distributed architectures and emerging technologies, the conceptual architecture framework can be even further divided, according to Figure B.2, into a distributed 3-tier architecture, a multi-tier architecture.

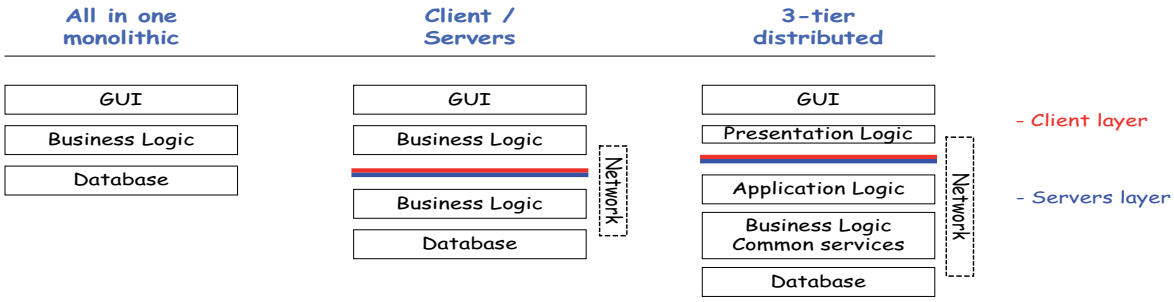

Figure B.2 — Evolution of distributed architectures

Such an architectural approach allows the federated nature of the healthcare organization to be reflected in the structure of its overall Healthcare Information System as a federation of systems, modules and components, individually responsible for the support of the healthcare organization's functional areas and individual organizational units. Each organizational service (e.g. a hospital admission) should be reflected in the supporting IT services, ensuring that organizational requirements are addressed from the information and computational viewpoints.

The fundamental benefits from such approach can be summarized as follows.

— Information service logic is independent from technological issues (i.e. multiple technologies and mechanisms can coexist for accessing the same services).

— Common information is separated from specific applications and accessible only through information services.

— Information and functional models must be well-documented and therefore open.

In order for the federated overall Healthcare Information System to be integrated and interoperate through the information services, principally two preconditions have to be met, namely the functional interoperability and the semantic interoperability.

The semantic interoperability is the fundamental pre-requisite and deals with the integration of the data and the consistency of concepts, terms, domain models and data models, the 'data/information architecture' from the overall point of view.

The functional interoperability deals basically with the ability to exchange data between system, modules and components through formalized interfaces based on consistent information.

The layer of the middleware services formalized by HISA has the fundamental responsibility of enabling such interoperability of the organization, by integrating and making available all information and all business logic of common relevance for the overall healthcare enterprise.

Bibliography

[1] Reynolds M., Wejerfeld I. *Short Strategic Study – Health Information Infrastructure – Final report*. CEN/TC 251/N00-074. Sept. 2000. Available from http://www.hisa-standard.org

[2] *Grundstruktur for Elektronisk Patientjournal (G-EPJ)*. Sundhedsstyrelsen (National Board of Health, Denmark). 2005. Available from http://www.sst.dk

[3] RM-ODP: *The Reference Model for Open Distributed Processing*. Available from http://www.rm-odp.net/.

[4] SAMBA, *Structured Architecture for Medical Business Activities*, Sweden 2003. Available from http://www.contsys.eu/documents/samba/english.htm

[5] EN 13940-1:2007, *Health Informatics — System of concepts to support continuity of care — Part 1: Basic concepts*

[6] EN 14822-1:2005, *Health Informatics — General purpose information components — Part 1: Overview*

[7] EN 14822-2:2005, *Health Informatics — General purpose information components — Part 2: Non clinical*

[8] EN 14822-3:2005, *Health Informatics — General purpose information components — Part 3: Clinical*

[9] CEN/TS 14796:2004, *Health Informatics — Data types*

[10] ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

[11] ISO 13606-1:2008, *Health informatics — Electronic health record communication — Part 1: Reference model*

[12] ISO 13606-4:2009, *Health informatics — Electronic health record communication — Part 4: Security*

[13] ISO/IEC 15414, *Information technology — Open distributed processing — Reference model — Enterprise language*

[14] ISO/IEC 19793, *Information technology — Open distributed processing — Use of UML for ODP system specifications*

[15] ISO/TS 22600 (all parts):2006, *Health informatics — Privilege management and access control*

[16] *Informative material on the implementation of the 12967 HISA series*. Available from http://www.hisa-standard.org

ICS 35.240.80

Price based on 51 pages