INTERNATIONAL STANDARD

ISO 12967-1

Second edition
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Health informatics — Service architecture (HISA) —

Part 1: Enterprise viewpoint

Informatique de santé — Architecture de service —

Partie 1: Point de vue de l'entreprise

Reference number
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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 12967-1:2009), which has been technically revised. The main changes compared to the previous edition are as follows:

— use of terms, definitions and concepts from ISO 13940:2015 (Contsys), with textual alignment throughout the document including figures, to the extent possible and beneficial;

— reference to further standards, such as HL7® and FHIR®;

— addition of abstraction layers supplementing the viewpoint descriptions;

— introduction of example functions from ISO/HL7 10781 supporting the use case examples of this document;

— addition of Annex C, Cross-Domain Interoperability, in line with the current (2020) ongoing ISO Interoperability and Integration Reference Architecture standardization initiative;

— updates to the Bibliography.

A list of all parts in the ISO 12967 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The healthcare organizational structure consists of networks of centres (hospitals of different types and sizes and outpatient clinics for primary and secondary care within a geographical area) 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.

A further aspect is related to quality management (see bibliography), where information management is an integrated part of quality management and the strategic and operative approaches for these two managerial aspects need to be co-ordinated to be effective. Clinical processes are comprehensive. Systematic and structured information management including medical knowledge management is required for high-level quality in effective healthcare systems.

The aims 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 should be supported by the architecture, which should 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.

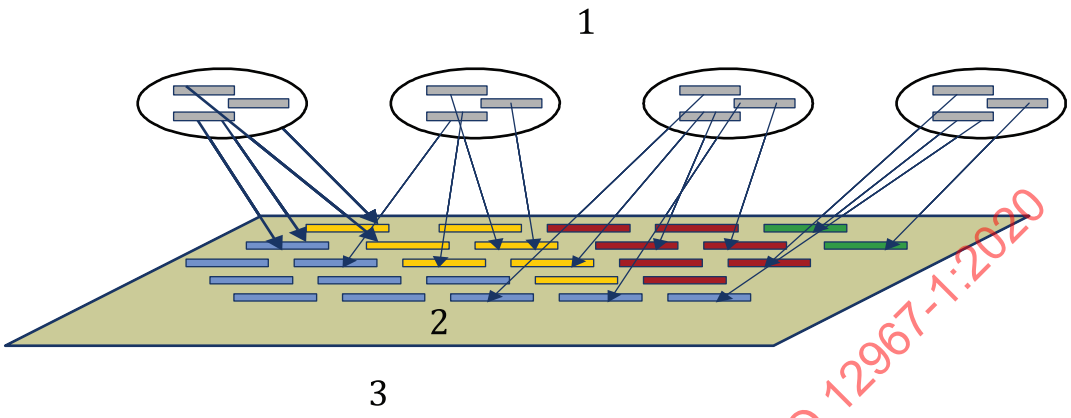
Standards and technological solutions already exist and will continue to be defined for supporting specific requirements, both in terms of in situ user operations and with respect to the movement of information. The architecture should be able to accommodate such requirements by allowing the specific models to be integrated with the complete information assets of the healthcare organization and e.g. 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 the ISO 12967 series 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.



Key

1 specific models and communication interfaces (e.g. CDA, FHIR, ISO 13606, DICOM)

2 common, neutral, organisation-wide HISA model

3 integrated and consistent heritage of all common enterprise data and common business logic

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

It is pointed out that the ISO 12967 series 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, the ISO 12967 series 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.

In line with the above HISA neither explicitly addresses major trends within healthcare in 2020 such as "Patient Engagement" or "Patient Registries/Patient Data Hubs". HISA nevertheless also supports these trends and might very well be used in connection herewith, providing further support for information exchange, to the benefit of the patient, or for structured and systematic information management regarding research, clinical databases, knowledge application and quality improvement.

The ISO 12967 series, 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, 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 (all parts)], and a concept model of healthcare (ISO 13940:2015). In the last ten years ISO, HL7 and CEN have increasingly collaborated and both the ISO 13606 (all parts) and ISO 13940:2015 have undergone major systematic

reviews as ISO standards. Besides these ISO standards, HL7 Service-Aware Interoperability Framework (SAIF) has served as a source of inspiration, the Australian E-health Interoperability Framework (eHIF, see bibliography) and a conference paper from 2016 "Digital Health Interoperability Frameworks: Use of RM-ODP Standards" as sources of input for this revision (see bibliography).

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 12967-1 to EN 12967-3 series on which the ISO 12967 series is based, currently serving as the basis for this revision.

The following characteristics of the ISO 12967 series 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. (Annex A provides short informative background information regarding the ISO/IEC 10746 (all parts) and Open Distributed Processing).

— 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 CDA, HL7 FHIR, ISO 13940:2015 (Contsys) and ISO 13606 (all parts). A separate mapping document between ISO 12967-2 and HL7 RIM was produced during the process for the first version of this ISO 12967 series. 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 concepts and principles shared with ISO 13606 (all parts), ISO 13940:2015 (Contsys) and the ISO 12967 series are aligned, originally stemming from CEN. But as the standards also reflect different, although complementary, scopes, purposes and objectives, as investigated during a joint "concurrent use" initiative, differences do exist.

Each part in the ISO 12967 series is self-consistent and is also independently utilizable for the intended purposes by different types of users (this document being more oriented to the managerial level, Parts 2 and 3 being more dedicated to the design activities). Nevertheless, it should 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 should be carried out according to the defined methodology to reserve 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 should 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 document.

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 document. 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 should 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 document. 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.

Annex C includes an explanation of ISO 23903:—[1)] and its relevance in regard to the ISO 12967 series, for integration with other standards such as ISO 13940.

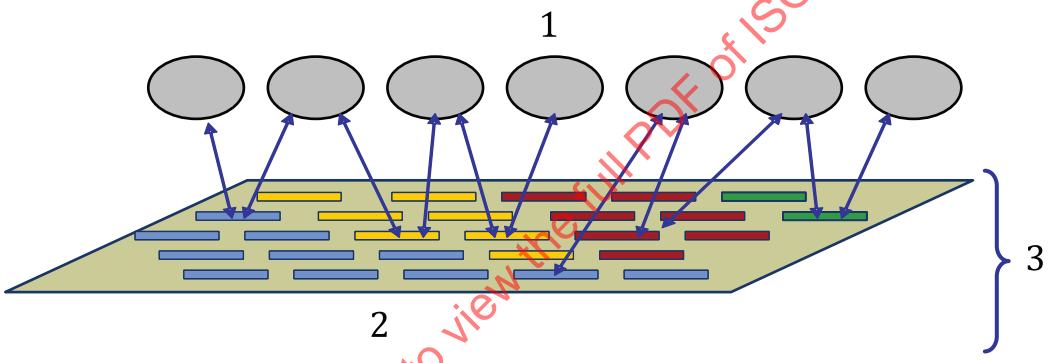
1) Under preparation. Stage at the time of publication ISO/DIS 23903:2020.

Health informatics — Service architecture (HISA) —

Part 1: Enterprise viewpoint

1 Scope

This document provides guidance and requirements 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.



Key

1 applications
2 middleware of objects integrating common data and common business logic
3 scope of ISO 12967-1

Figure 2 — Scope

This document 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 document.

The language and notations used here for specifying the architecture are based on UML (Unified Modeling 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. Accordingly, methodology formalized by the Engineering and Technology viewpoints of the RM ODP Reference Model can be followed for the implementation.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 (all parts), *Information technology — Open Distributed Processing — Reference model*

ISO 12967-2:2020, *Health informatics — Service architecture — Part 2: Information viewpoint*

ISO 12967-3:2020, *Health informatics — Service architecture — Part 3: Computational viewpoint*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1 Healthcare

3.1.1
healthcare
care activities, services, management or supplies related to the health of an individual

Note 1 to entry: This includes more than performing procedures for subjects of care. It includes, for example, the management of information about patients, health status and relations within the healthcare delivery framework and may also include the management of clinical knowledge.

[SOURCE: ISO 13940:2015, 3.1.1]

3.1.2
health issue
representation of an issue related to the health of a subject of care as identified by one or more healthcare actors

[SOURCE: ISO 13940:2015, 6.3]

3.1.3
healthcare matter
representation of a matter related to the health of a subject of care and/or the provision of healthcare to that subject of care, as identified by one or more healthcare actors

[SOURCE: ISO 13940:2015, 6.2]

3.1.4
health state
physical and mental functions, body structure, personal factors, activity, participation and environmental aspects as the composite health of a subject of care

[SOURCE: ISO 13940:2015, 6.5]

3.1.5
health condition
observed or potential observable aspects of the health state at a given time

[SOURCE: ISO 13940:2015, 6.4]

3.1.6
observed condition
health condition observed by a healthcare actor

[SOURCE: ISO 13940:2015, 6.4.1]

3.2 System concepts

3.2.1
information service
ability of the system to provide a defined set of output information based on a defined set of input information

Note 1 to entry: The term information service is consistently used in this document for the services provided by the information system.

Note 2 to entry: The healthcare information services are the healthcare related services provided by healthcare information systems.

3.2.2
middleware
enabling technology of enterprise application integration describing a piece of software that connects two or more software applications so that they can exchange data

Note 1 to entry: 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 to entry: 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 document, the usage of the term "middleware" is in the context of HISA, related to the services.

3.2.3
enterprise application integration
use of software and computer systems architectural principles to integrate a set of enterprise computer applications

3.2.4
object
model of an entity, characterized by its behaviour and its state, encapsulated and distinct from other objects

Note 1 to entry: This definition is about "object" in the architectural sense [in line with the ISO/IEC 10746 (all parts)]. This does not preclude the use of the word in the natural language sense as an entity itself, where e.g. a "process object" of a healthcare/clinical process is the health state of a subject of care.

[SOURCE: ISO/IEC 10746-2:2009, 8.1, modified — shortened.]

3.2.5
enterprise object
object modelling an enterprise entity

3.2.6
class
abstraction of the knowledge and behaviour of a set of similar things

Note 1 to entry: Class in UML is a description of a set of objects that share the same attributes, operations, methods, relationships, and semantics.

[SOURCE: ISO/IEC/IEEE 24765:2017, 3.577, modified — Note 1 to entry substituted.]

3.3 Concepts relating to organization

3.3.1
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

Note 1 to entry: An organization can be public or private.

Note 2 to entry: The scope of an organizational structure can include relevant interfaces to external organizations.

[SOURCE: ISO 9000:2015, 3.2.1, modified — Note 1 to entry has been simplified and Note 2 to entry substituted.]

3.3.2
healthcare actor
organization or person participating in healthcare

[SOURCE: ISO 13940:2015, 5.2, modified — Note 1-3 to entry omitted.]

3.3.3
healthcare provider
healthcare actor that is able to be assigned one or more care period mandates

[SOURCE: ISO 13940:2015, 5.2.3, modified — Note 1-3 to entry omitted.]

3.3.4
subject of care
healthcare actor with a person role; who seeks to receive, is receiving, or has received healthcare

Note 1 to entry: Among synonyms are patient and subject of healthcare

[SOURCE: ISO 13940:2015, 5.2.1, modified — Note 1 to entry substituted and Examples omitted.]

3.3.5
healthcare organization
healthcare provider having an organization role

[SOURCE: ISO 13940:2015, 5.2.3.1, modified — Note 1-4 to entry and Examples omitted.]

3.3.6
role
function or position

[SOURCE: ISO 13940:2015, 3.3.5]

3.4 Community concepts

3.4.1
community
configuration of objects formed to meet an objective

Note 1 to entry: The objective is expressed as a contract, which specifies how the objective can be met.

3.4.2
federation
community of domains

3.4.3
objective
practical advantage or intended effect, expressed as preferences about future states

Note 1 to entry: Some objectives are ongoing, some are achieved once they are met.

3.5 Behaviour concepts

3.5.1
resource
asset that is utilized or consumed during the execution of a process

Note 1 to entry: Allocation of a resource may constrain other behaviours for which that resource is essential.

Note 2 to entry: 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).

[SOURCE: ISO 13940:2015, 3.4.1, modified — Note 1-2 to entry substituted.]

3.5.2
process
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: 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 2 to entry: Inputs to a process are generally outputs of other processes.

Note 3 to entry: The health care process is provided in the health care enterprise.

Note 4 to entry: Processes in an organization are generally planned and carried out under controlled conditions to add value.

Note 5 to entry: A process where the conformity of the resulting output cannot be readily or economically verified is frequently referred to as a "special process".

Note 6 to entry: 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 (see respective definitions in ISO 9000:2015, 3.12.8, 3.12.9, 3.12.10, and 3.12.5). 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 to entry: 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 to entry: 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.

[SOURCE: ISO 9000:2015, 3.4.1, modified — Note 1 to entry substituted, Note 2 to entry simplified, Note 3 to entry substituted, Note 6 to entry substituted, Note 7 and 8 to entry added.]

3.5.3
step
abstraction of an action, used in a process, that might leave unspecified objects that participate in that action

3.5.4
service
result of a process

Note 1 to entry: 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 to entry: The healthcare services are the services taking place within a healthcare organization.

3.5.5
workflow
series of activities necessary to complete a task

Note 1 to entry: 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.

Note 2 to entry: In terms of HISA, a workflow may involve a number of HISA services, involving the organization in the provision of more complex objectives, according to agreed procedural rules.

3.5.6
healthcare activity
activity intended directly or indirectly to improve or maintain a health state

[SOURCE: ISO 13940:2015, 7.2, modified — Note 1-3 to entry and Examples omitted.]

3.5.7
healthcare activity element
element of healthcare activity that addresses one type of purpose

Note 1 to entry: Healthcare activity is a complex concept that can be subdivided in elements that represent different purposes with the action. The different purposes could be direct (healthcare investigation and healthcare treatment that directly involves the subject of care) or indirect (healthcare assessment, healthcare evaluation, healthcare documenting or healthcare activity management) that do not necessarily directly involve the subject of care.

[SOURCE: ISO 13940:2015, 7.2.7]

3.5.8
care plan
dynamic, personalized plan including identified needed healthcare activity, health objectives and healthcare goals, relating to one or more specified health issues in a healthcare process

[SOURCE: ISO 13940:2015, 9.2, modified — Note 1-5 to entry and Examples omitted.]

3.5.9
healthcare goal
desired achievement of one or more healthcare activities, considered as an intermediate operational step to reach a specific health objective

[SOURCE: ISO 13940:2015, 9.2.6, modified — Note 1 to entry and Examples omitted.]

3.5.10
protocol
customized clinical guideline

Note 1 to entry: A protocol is more precise than a clinical guideline.

Note 2 to entry: Protocols are often presented in a formal manner with respect to the expected behaviours and roles of healthcare actors.

[SOURCE: ISO 13940:2015, 9.2.4.1, modified — Examples omitted].

3.5.11
clinical guideline
set of systematically developed statements to assist the decisions made by healthcare actors about healthcare activities to be performed with regard to specified health issues

Note 1 to entry: Clinical guidelines are usually rather generic and they concern no actual subject of care in particular. While they generally reflect a broad statement of good practice, they may sometimes include multiple operational details.

[SOURCE: ISO 13940:2015, 9.2.4, modified — Note 2 to entry and Examples omitted.]

3.5.12
clinical process
healthcare process encompassing all healthcare provider activities and other prescribed healthcare activities that addresses identified or specified health issues

[SOURCE: ISO 13940:2015, 8.2.1, modified — Note 1-7 to entry omitted.]

3.5.13
task
activities required to achieve a goal

[SOURCE: ISO/IEC 25063:2014, 3.14]

3.6 Policy concepts

3.6.1
policy
set of rules related to a particular purpose

Note 1 to entry: A rule can be expressed as an obligation, an authorization, permission or a prohibition.

Note 2 to entry: Not every policy is a constraint. Some policies represent an empowerment.

3.6.2
authorization
prescription that a particular behaviour is not prevented

Note 1 to entry: Unlike permission, an authorization is an empowerment.

3.7 Accountability, responsibility and time concepts

3.7.1
party
person or group performing a role in relation to the business of a specific community or domain

Note 1 to entry: Examples of parties include enterprise objects representing natural persons, legal entities, governments and their parts, and other associations or groups of natural persons.

[SOURCE: ISO 8459:2009, 2.33 and ISO 13940:2015, 3.3.3, modified — Note 1 to entry added.]

3.7.2
commitment
obligation by one or more of the participants in an act to comply with a rule or perform a contract

Note 1 to entry: 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.

3.7.3
declaration
action that establishes a state of affairs in the environment of the object making the declaration

Note 1 to entry: 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.

3.7.4
evaluation
action that assesses the value of something

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

Note 2 to entry: 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.

3.7.5
prescription
act that establishes a rule

Note 1 to entry: Specialized meaning in healthcare where a prescription of medicinal products establishes the rule that medication can be given by a pharmacy

3.7.6
agent
active enterprise object that has been delegated something (authorization, responsibility, provision of a service, etc.) by, and acts for, a party (in exercising the authorization, carrying out the responsibility, providing the service, etc.)

Note 1 to entry: 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 to entry: 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.

Note 3 to entry: A specification may state that, in its initial state, an active enterprise object is an agent of a party.

3.7.7
principal
party that has delegated (authority, a function, etc.) to another

3.7.8
demand for care
demand for healthcare provider activities expressed by a healthcare actor

[SOURCE: ISO 13940:2015, 11.3, modified — Note 1-3 to entry and Examples omitted.]

3.7.9
healthcare mandate
mandate (commission) based on a commitment and either an informed consent or an authorization by law, defining the rights and obligations of one healthcare actor with regard to his involvement in healthcare processes performed for a specific subject of care

[SOURCE: ISO 13940:2015, 11.2, modified — Note 1-4 to entry omitted.]

3.7.10
healthcare commitment
acceptance of a healthcare mandate by the healthcare actor to whom it is assigned

[SOURCE: ISO 13940:2015, 11.2.10, modified — Note 1-2 to entry omitted.]

3.7.11
mandated period of care
set of healthcare activity periods where a healthcare provider is mandated to perform the healthcare activities required to address specific health needs

[SOURCE: ISO 13940:2015, 10.2.1, modified — Note 1-5 to entry and Examples omitted.]

3.7.12
contact
interaction between a subject of care and one or more healthcare personnel

Note 1 to entry: According to ISO 13940:2015 'contact' takes place during 'contact period' with a multiplicity of 1 to 1, and 'contact period' is a specialization of 'healthcare activity period', which is identical with 'contact' in its former definition (former ISO 13940, EN 13940-1:2007).

[SOURCE: ISO 13940:2015, 10.2.2.1.1, modified — Note 1 to entry added.]

3.8 Information management

3.8.1
healthcare information
information about a person relevant to his or her healthcare

[SOURCE: ISO 13940:2015, 3.9.4]

3.8.2
health record component
part of a health record that is identifiable for the purposes of referencing and revision

[SOURCE: ISO 13940:2015, 12.2.3, modified — Note 1-2 to entry omitted.]

3.8.3
professional health record
health record held under the responsibility of one healthcare provider and maintained by one or several healthcare professionals

[SOURCE: ISO 13940:2015, 12.2.1, modified — Note 1 to entry and Examples omitted.]

3.8.4
health record
data repository regarding the health and healthcare of a subject of care

[SOURCE: ISO 13940:2015, 12.2, modified — Note 1-2 to entry omitted.]

3.8.5
data
reinterpretable representation of information in a formalized manner suitable for communication, interpretation or processing

Note 1 to entry: Data can be processed by humans or by automatic means.

[SOURCE: ISO 13940:2015, 3.9.1 and ISO/IEC 2382:2015, 2121272, modified]

3.8.6
information
knowledge concerning objects that within a certain context has a particular meaning

Note 1 to entry: Facts, events, things, processes, and ideas, including concepts, are examples of objects.

Note 2 to entry: Information is something that is meaningful. Data might be regarded as information once its meaning is revealed.

[SOURCE: ISO 13940:2015, 3.9.5 and ISO/IEC 2382:2015, 2123204, modified]

4 Symbols and abbreviations

CDA	Clinical Document Architecture (HL7)
ECG	Electrocardiogram
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resources (HL7)
HISA	Health Informatics Service Architecture (ISO 12967 series)
ODP	Open Distributed Processing
RIM	Reference Information Model (HL7)
SOA	Service Oriented Architecture
UML	Unified Modeling Language

5 Methodology for the specification of the architecture

5.1 General

This clause describes the methodology adopted by this document 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.

NOTE The ODP approach described does not include the formalization of the process according to which a system is identified, planned, designed and implemented but can nevertheless provide guidance for it.

5.2 provides an overview on the viewpoint-based ODP methodology. 5.3 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.

5.2 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 document 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 can be described as a SOA, e.g. in the form of web services.

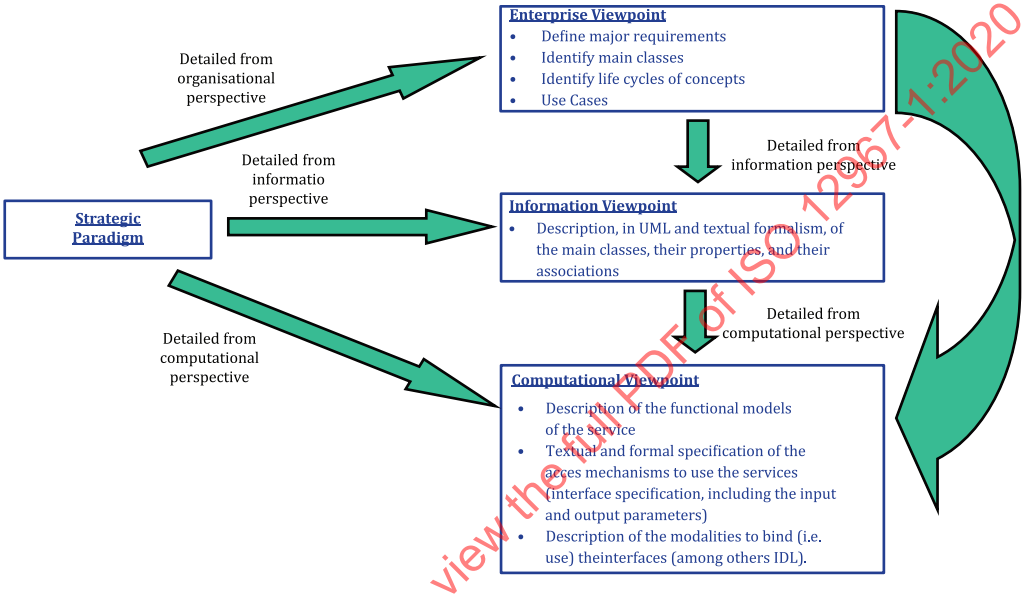


Figure 3 — Three (of five) ODP viewpoints detailed in HISA

5.3 The HISA specification procedure

5.3.1 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 6.2 further details what the content of a strategic paradigm of an enterprise includes.

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.

5.3.2 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:

— identification of the business processes with relevant scope and objectives with regard to the overall mission of the healthcare enterprise;

— 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;

— 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 conceivable in the whole information assets of the enterprise.

The specification of each elementary activity shall include:

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

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

c) 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.

5.3.3 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.

5.3.4 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.

5.4 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.

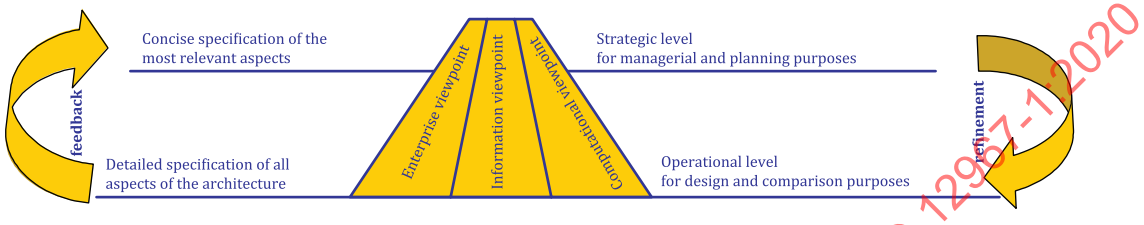


Figure 4 — Iterative, incremental specification process

5.5 Viewpoints specification languages, notations and levels of abstraction

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 5.2 to 5.4.

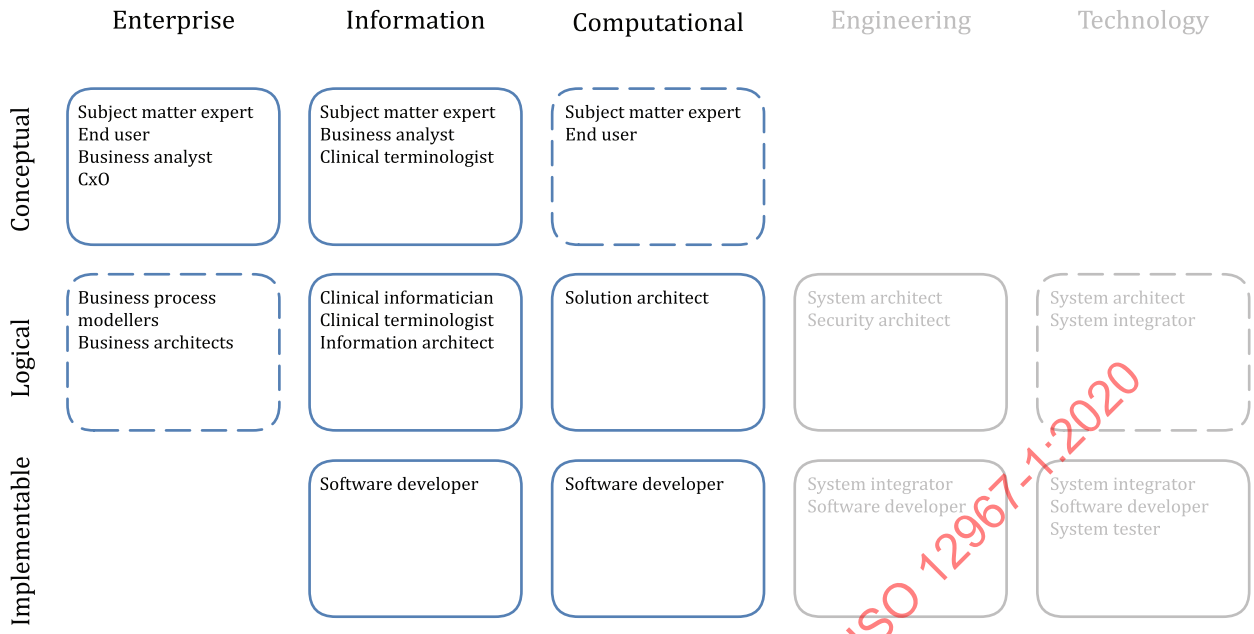
The ODP viewpoints may be extended with 3 levels of abstraction, in line with generally known Enterprise Architecture Frameworks (e.g. EA3, TOGAF, Zachmann) and in particular the Australian E-health Interoperability Framework (see Bibliography). These levels of abstraction are:

— **Conceptual**: The conceptual layer focuses on the subject matter expert's view of a specific area. The details of the structure and processing of the system may not be specified. High-level UML class diagrams could be used to depict key classes and their relationships.

— **Logical**: The logical layer introduces more detail in terms of the behavioural and information descriptions of the IT solution. The logical layer will typically use formalised notation language such as UML. Some conceptual models may be categorized as logical models depending on the circumstances. Although the distinction between 'conceptual' and 'logical' may be blurred at times, the key point is that all the relevant models should be provided in order to ensure a complete system specification.

— **Implementable**: This layer is concerned with the specific choice of technology used to describe the components of the IT system.

The combination of viewpoints, abstraction layers and stakeholder involvement is depicted below in Figure 5. Key cells are shown with solid lines, and the optional cells with dashed lines.



NOTE Engineering and technology viewpoint are greyed out (as out of scope).

Figure 5 — Viewpoints, abstraction layers and stakeholders

This document 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 services, complemented with textual descriptions on the scope and functionalities of each service, the formalization of the datatypes used at interface level and by the IDL specification of the interface of each service.

6 HISA overview

6.1 General requirement

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.

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 document;

   2) implement the information model specified in the “information viewpoint” of this document;

   3) provide the services specified in the “computational viewpoint” of this document.

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

d) It shall represent an autonomous and replaceable set of components of the physical architecture of the information system.

NOTE Annex B provides an informative brief description of the federative characteristics of the health informatics service architecture in regard to the federated nature of the healthcare organization, and how this can be related to overall conventional technical IT system architecture.

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 healthcare actors perform healthcare activities, related to care delivery, as well as to administrative and managerial requirements of the enterprise.

The execution of a healthcare activity usually creates outcomes which may include healthcare 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 healthcare 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 healthcare activity performed.

Due to the particular nature of the healthcare information (either generated from the execution of specific activities, or pre-existing in the system), the management of such information shall conform to specific provisions in terms of accountability, validation and traceability. Such information 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 healthcare 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 healthcare activities and information.

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 healthcare, organizational and managerial purposes.

Electronic interactions among different organizations and information systems are usually based on messages, or webservices carrying similar rich content as payload, adhering to communication standards.

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 contacts of the subject of care with the organization itself, including the interactions with the funding organizations.

— **Healthcare activity management workflow (carer-centric)**

  This workflow relates to users' activities related to the management of the different types of healthcare 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.

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

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

Other services of the middleware shall support (both independently and complementary to the abovementioned 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 information 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 healthcare, organizational and managerial purposes) the managed information.

The middleware shall also provide services enabling the structuring of information 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 and webservices).

Clause 9 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.

a) 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.

b) Healthcare activity management objects

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

c) Healthcare information objects

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

d) 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.

e) 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.

f) 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.

g) Messaging objects

These objects shall organize and store the information necessary for supporting the structuring of information and the communications with other systems through messaging mechanisms or webservices carrying similar rich content as payload, 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.

ISO 12967-2:2020, Clause 5, 6 and 7 provide 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) **High-level eHealth business-related information services**, implementing complete business transactions related to the supported users' activities, also involving multiple objects and information according to the specific rules of the organization.

ISO 12967-3:2020, Clause 5 and 6 provide a detailed specification of the services that shall be provided by the middleware.

7 Methodology for extensions

This document 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 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 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 12967-2:2020, Clause 5, 6 and 7. 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 information, 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 12967-3:2020, Clause 5 and 6. 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

8.1 General

Two types of conformance criteria are identified, according to the twofold scope of this document 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. Both types of conformance criteria are required to be met.

8.2 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.

The following documents shall be delivered:

a) the strategic paradigm;

b) the enterprise viewpoint;

c) the information viewpoint;

d) 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 document may be the healthcare enterprise itself but will often be done in cooperation with a HISA platform product supplier and HISA specialist consultancy companies.

8.3 Conformance of middleware products to the HISA architectural requirements

Products claiming conformance to this document

a) shall be described by means of the methodology and the documents defined in Clause 5,

b) shall implement middleware conforming to the requirements defined in Clause 6,

c) shall implement an information model comprising all objects and conforming to the requirements defined in ISO 12967-2:2020, Clause 5, 6 and 7,

d) shall provide, at least, all services defined in ISO 12967-3:2020, Clause 5 and 6,

e) shall be extensible to accommodate local and new standardization requirements according to the criteria defined in Clause 7.

The product should, by its realization of HISA, encompass the EHR-related ISO standards and their national implementations 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. As only the top three ODP viewpoints (Enterprise, Information and Computation) are addressed in the ISO 12967 series, compliance is 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 Should suppliers provide only a subset of the HISA services, a partial conformance to the relevant HISA services can be declared. Thus, if addressing only parts of the HISA information model with its services, compliance can be declared defining what is included and excluded.

NOTE 3 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 Overview

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,

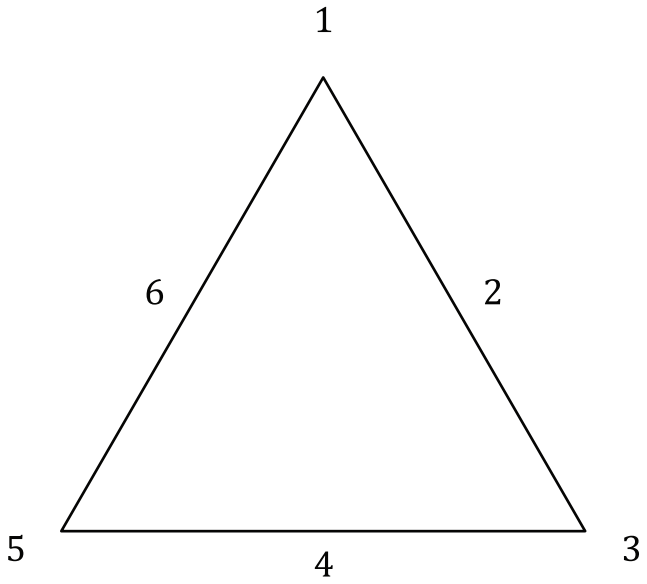
— a medical/clinical perspective, and

— 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 document is mainly on the intra-enterprise level and the two last bullets. The descriptions serve to identify common, essential healthcare services.

9.1.2 The regional, inter-enterprise perspective

At a high level of abstraction, Figure 6 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.



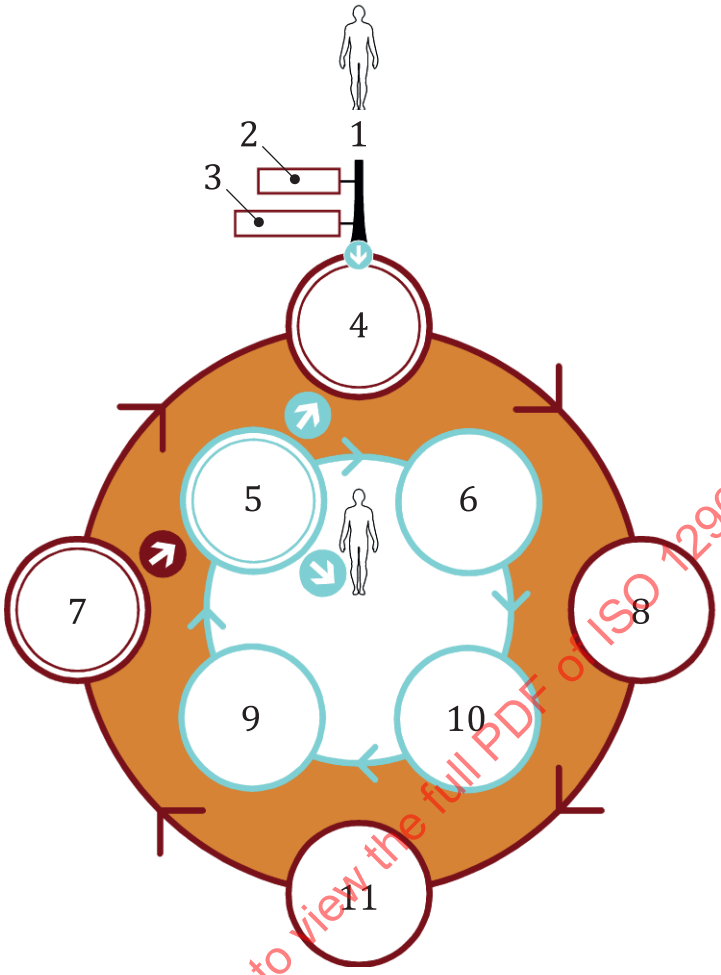
Key

1 patients (customers)
2 insurance premiums taxes
3 purchasers (payers)
4 contracts billing reimbursement
5 providers
6 services payments

Figure 6 — 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 7 presents one conceptual process model.



Key

1	input health state
2	health issue
3	demand for care
4	healthcare needs assessment
5	healthcare needs assessment
6	plan treatment activities
7	evaluate investigation results
8	plan investigation activities
9	evaluate treatment results
10	perform treatment activities
11	perform investigation activities
	investigation
	treatment
	identified health conditions
	health state

Figure 7 — Main concepts of a clinical process (from ISO 13940:2015, A.5)

A clinical process model describes the healthcare *activities* and the value added to the process object by describing the health *conditions* that represent the health *state*. The main concepts in a process model are the health *conditions* and the healthcare *activities*.

The healthcare *activities* and the health *conditions* motivating and/or resulting from these activities in any applied healthcare *process* can be categorized and/or traced from the clinical process model. The process model used to give the clinical context for the concepts in ISO 13940:2015 is shown in Figure 7. It describes:

— a generic healthcare/clinical process through the inputs and outputs (health *state*);

— the way the inputs are observed, assessed and transformed (health *conditions*);

— the concepts for activities performed (healthcare *activities*);

— healthcare investigations illustrated by the outer red circle;

— healthcare treatments illustrated by the inner blue circle; and

— the additional concepts needed for the performance (management or resource support).

The concepts and steps in the clinical process model are further described in ISO 13940:2015.

9.1.4 The operational/clinical and organizational process model perspective

9.1.4.1 Modelling of healthcare

In healthcare, "healthcare activity" is a well-established term for everything that is carried out in the provision of care for patients. A healthcare activity is an "activity intended, directly or indirectly, to improve or maintain a health state". Healthcare activities commonly includes interaction between healthcare professional actors and a patient/subject of care. A purpose or an intention of the performance can always be identified. Concerning patient-related activities, healthcare professional actors (one or more) can be pointed out as responsible for prescribing and/or performing the complete or part of the activity.

The clinical process includes the interaction between an individual patient and all healthcare activities prescribed or performed by healthcare providers related to specified health issue(s) of the patient. A healthcare activity in a clinical process is a deliberate act, and legal rules for responsibility makes it mandatory with responsible actors who are authorized to perform the type of activity. Activities in other processes can influence the clinical process. The results of processes for e.g. management and/or resource support are intentionally influencing the clinical process. Different kinds of unintentional events also can influence the clinical process. Such events may cause aberrations in the result of an activity and/or a clinical process.

Other types of processes in healthcare organizations are processes for basic education of healthcare personnel and for research. Examples of other processes interacting with clinical process are the management, resource support, information management and financial management processes.

The core process is called the clinical process in healthcare. The process object is the health state of the subject of care (synonymous with "patient", which is used as a short form). Aspects of a health state are health conditions. The condition can represent a circumstance in the health state of the patient. A health condition assessed to be a problem is a health problem. The activities encompassed in a clinical process are only those which clarify and/or influence the health state of the patient.

A demand for care, which has been received by a healthcare provider, is a potential permission/consent for the provider to provide healthcare to the person who is subject to the demand for care. It is a healthcare mandate when the provider has concluded a healthcare commitment. When the mandate has become an effective care mandate, it is a formal framework for responsibilities in the clinical process.

9.1.4.2 Healthcare process

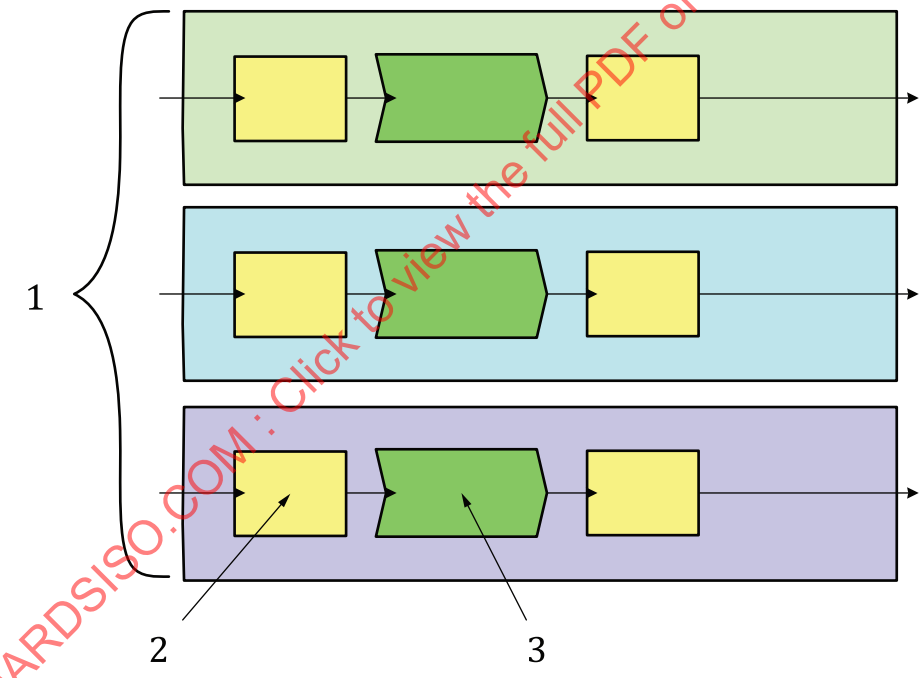
9.1.4.2.1 General

The following process descriptions in this and the following subclauses 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 health state of the subject of care, represented by health conditions, is refined. The intention in the process is that the health state improves. However, it is only what is conceived that can be registered, and be the basis for how success in the process can be assessed. A health condition can be favourable or unfavourable, and a health problem is a specialisation of a health condition.

9.1.4.2.2 Notation rules for processes

In each process, the process object is traced from activity to activity. The process 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 process object (see Figure 8).



Key

1 process package
2 process object
3 activity

Figure 8 — The symbols of the processes each with its own activity and object

9.1.4.2.3 Care of an individual subject of care

The care of an individual subject of care basically, from the provider perspective, can be considered to consist of two phases of clinical processes.

— Assessment of the 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. Healthcare investigations and healthcare treatments are performed for clarifying and influencing the health state of the subject of care.

9.1.4.2.4 Assessment of the demand for care

A demand for care is received by a healthcare provider. The assessment is based on the reason for contact in the demand for care and concludes if there are any healthcare activities motivated. This assessment is a healthcare needs assessment. To do this, the type of condition should be identified further. Then this type of condition should be matched against the service repository, to see if there are clinical processes available to achieve 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. Together with the subject of care's informed consent healthcare activity mandates exist. If this fails, it can either be decided to reject the demand for care, or the demand for care can be assessed in further, repeated healthcare need assessments.

Figure 9 depicts the assessment of demand for care, and the possible use of information services provided by the system, to support the process. Information services are used for registering the demand for care, to possibly access any previous healthcare information for the patient, to retrieve the catalogue concerning healthcare services provided and to register the healthcare needs assessment and the resulting decision regarding healthcare commitment.

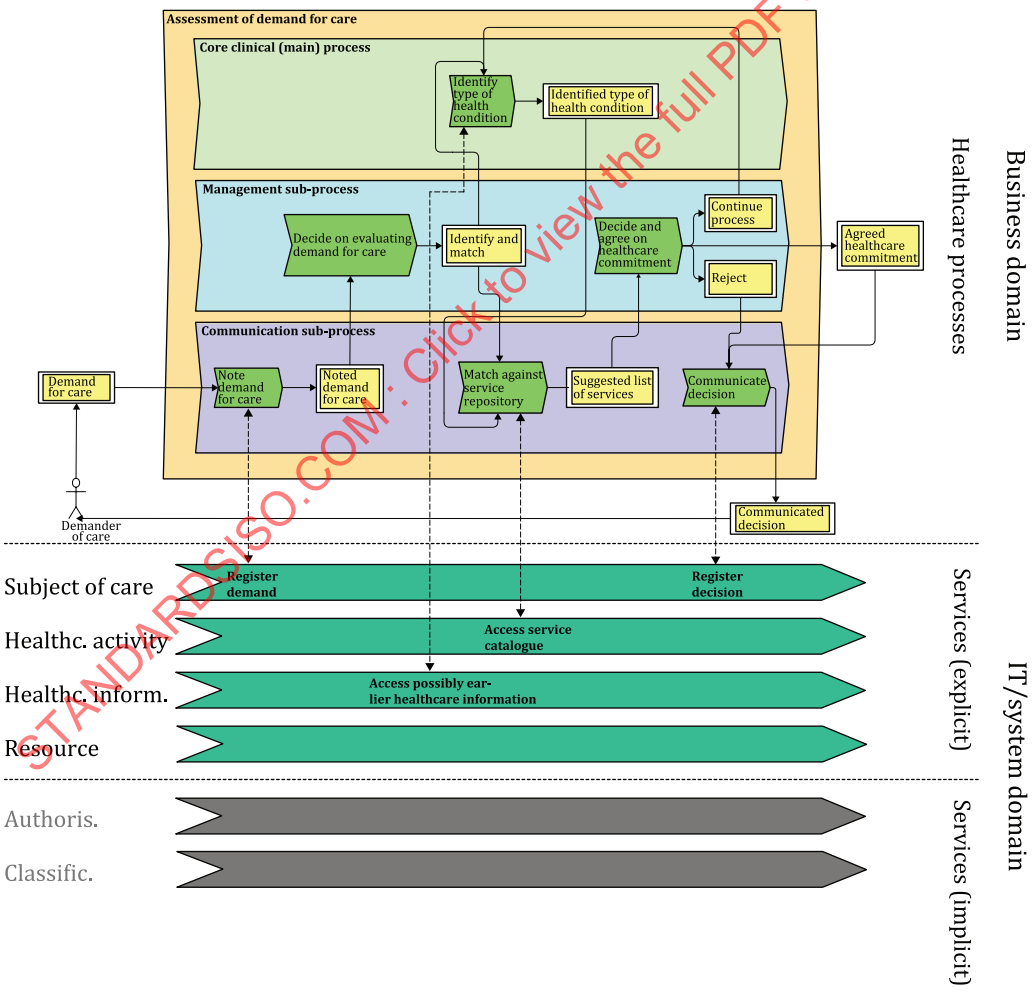


Figure 9 — Assessment of demand for care, and information services

9.1.4.2.5 Realize healthcare commitment

The healthcare commitment is registered in the care plan. The health problems of the patient are formulated, 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 possible available activities to solve the problems stated and achieve the goals can be planned.

The healthcare activities in the care plan are carried out in the clinical 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 observed conditions of the patient. 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 should be evaluated in the light of the new observed conditions. Several iterations can be carried out, in a healthcare flow: needs assessment for investigations, perform investigations, evaluations, needs assessment for treatment, perform treatment and evaluate the effect on the health state of the subject of care.

If it is decided to terminate the process from the responsible provider without resolving the healthcare needs, it should be verified that the patient is taken care of (the process cannot be terminated without agreement on the responsibility for the patient).

Figure 10 depicts the realization of healthcare commitment, and the possible use of information services provided by the system, to support the process. Information services are used for registering the demand for care, the healthcare needs assessments and the healthcare commitment. The purposes are to access any healthcare information 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 healthcare information for evaluation of the patient, and to register decisions.

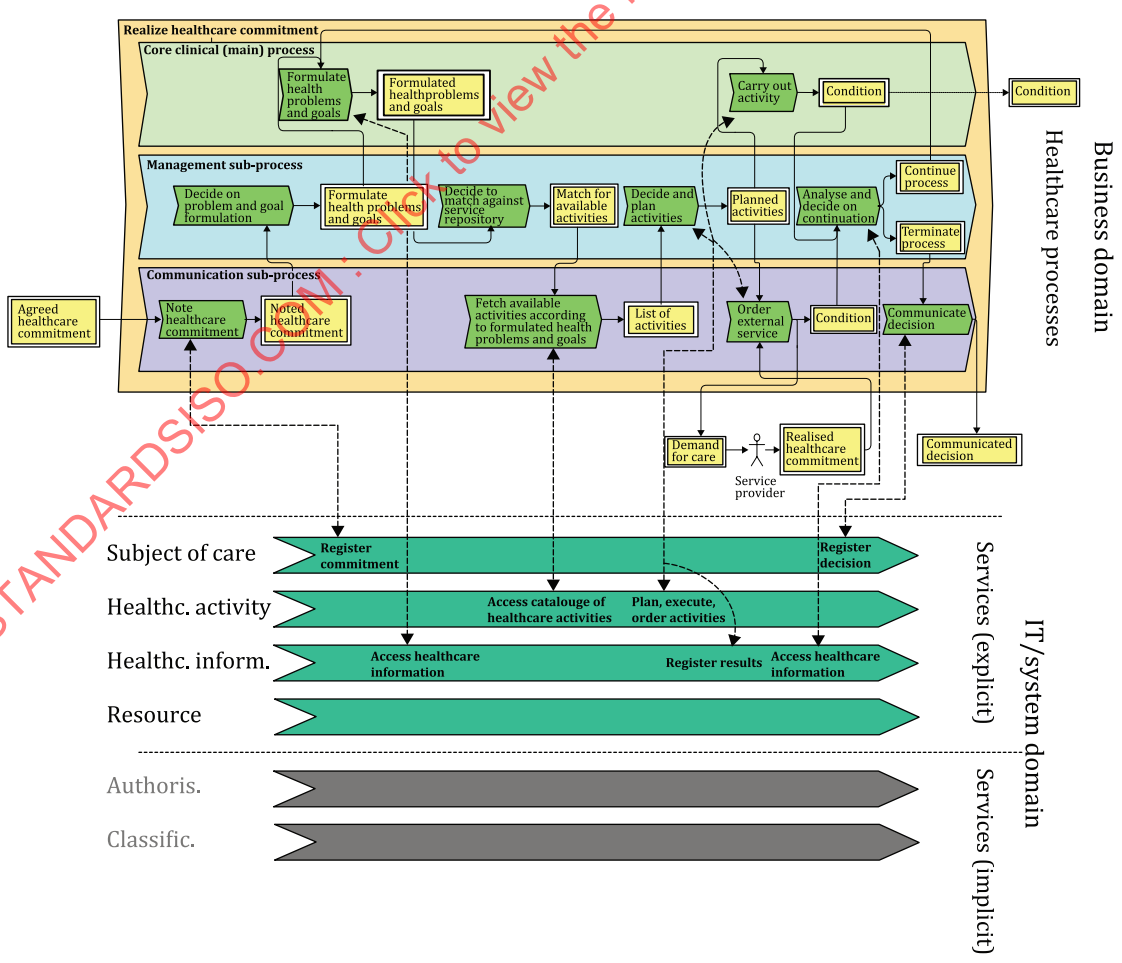


Figure 10 — Realization of healthcare commitment, and information services

9.1.5 The information services and their complexity

In the previous subclauses, a number of healthcare activities and healthcare 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 information-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 healthcare 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 information architecture provided by the information services, and flexibility of the information services recommended.

In line with the heterogeneous but interrelated nature of the healthcare processes, on, for example, the administrative, clinical and intellectual levels, the information services should be context aware. This is also a precondition for the ability of the information services and their information content, to be mappable 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 11. The diagram follows the concepts defined in the document in Clause 3 and largely coming from ISO 13940:2015, with a few exceptions (e.g. individual user, authorisation profile).

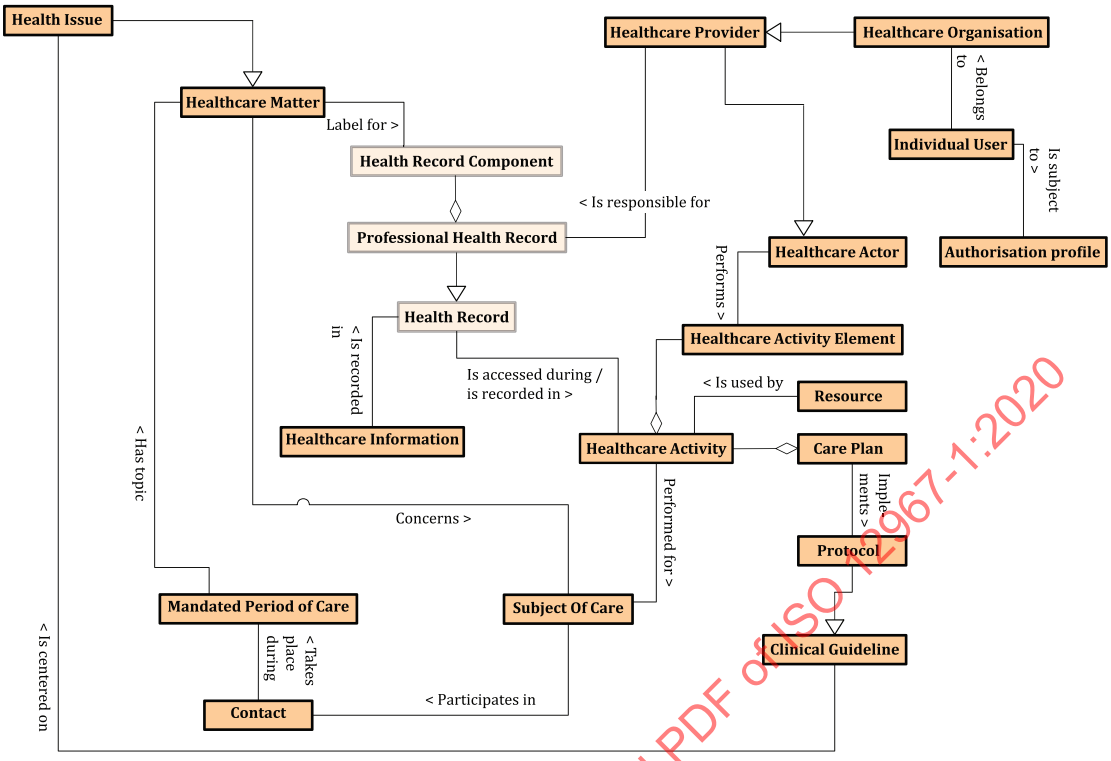


Figure 11 — The overall/main HISA classes and their relation (paradigm described in 6.2)

The classes Health Record Component, Professional Health Record and Health Record are opaque as only intrinsically part of what a HISA compliant system should include, to the extent of its EHR support and accordance with other standards including ISO 13940:2015 and ISO 13606 (all parts). In terms of HISA, the class Healthcare Information is supported directly (instead of Health Record Component, Professional Health Record and Health Record as such), as a rather generic concept, defined and described only under ISO 13940:2015, Clause 3.

The HISA information models in ISO 12967-2:2020, Clause 5, 6 and 7 are not a one-to-one unfolding of Figure 11, but addressing key elements hereof such as Healthcare Information, with a viewpoint of the information constructs needed from a system perspective.

ISO 13940:2015 is mainly about the business domain itself, whereas HISA is mainly about the IT domain. HISA defines models with classes and services related hereto, in the sense of what should be supported in the enterprise domain at an overall level. ISO 13940:2015 defines detailed concepts and relations in the business domain.

ISO 13940:2015 thus focuses on the concepts and processes, viewing information as managed by a health record. For the information to be in accordance with the concepts and processes are key, but not as much how this is managed. HISA focuses on the services, through which information is created, read, updated and deleted in connection with and as a result of many healthcare activities. The management of information through the services are key, but not as much the information itself. HISA refers to only a fraction of the concepts and terms in ISO 13940:2015, for a complete coverage of all the concepts and terms of the business domain ISO 13940:2015 is highly recommended.

Further general information on mapping between different domains and models with different purpose, levels and scopes is provided in Annex C.

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. healthcare information, healthcare activity information, Electronic Health Record manipulation, etc.).

NOTE The strategic paradigm (6.2) and the overall diagrammatic representation of it (Figure 11) together with the following subclauses with general requirements, workflows and clusters of users' activities, constitute rationale and basis for the complete HISA information model in ISO 12967-2:2020, Clause 5, 6 and 7 and the HISA information services in ISO 12967-3:2020, Clause 5 and 6.

9.3 General information requirements for all users' activities

9.3.1 General

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 healthcare actor that created the object instance;

— time and date of last modification of the instance;

— identification of the healthcare actor that executed the last intervention on the instance;

— owner of the object (the healthcare actor);

— 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 (healthcare actor);

— identification of previous version.

9.3.5 Auditing

In order to meet security related and legislative requirements, 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 healthcare actor;

— input and output information exchanged with the service calling healthcare actor.

9.3.6 Handling of life cycle

Some of the central objects in healthcare have a life cycle (such as mandated period of care, contact, healthcare information, demand for care, healthcare activity and care 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 healthcare actor.

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

— status;

— date and time of status change;

— responsible healthcare actor.

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 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 summary personal, healthcare and epidemiological information on the individual patients, 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 information, 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 healthcare organizations, comprising in-patients and ambulatory out-patients, is strongly recommended for any 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 information services, first of all, consideration shall 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 undergoes a life cycle starting from his/her registration as a person, (not yet necessarily being a patient), then registering his/her treatment with all of the describing attributes, up to the registration of the end of the treatment. 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 healthcare actors.

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 document to define any specific detail for such information which will be specified in individual cases.

From the organizational and clinical points of view, these 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. 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 organization. The admitting organizational 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 healthcare actor, organizational unit, referral's diagnosis, etc.);

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

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

— statistical/demographic/epidemiological information 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 properties of the patient's stay in the healthcare facility (date, actual type of contact, admitting organizational unit – in certain instances even defined by coordinates or address

– and admission diagnosis) and consider the contact in progress (i.e. 'current' status). If the contact was foreseen, the information entered at preadmission should be updated according to the actual information 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 healthcare actor, organizational unit, referral's diagnosis, etc.);

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

— healthcare information that may be significant for the planned contact (generic healthcare information, 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 organizational unit or to another unit. At such transfer, several elements of information should be specified, including the new patient location (organizational unit, service-point), date and time of the transfer, reason for transfer and diagnosis at the transfer. There are also other issues that should 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 organizational unit/service-point (e.g. the time he/she is undergoing surgery or another healthcare 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 should 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

9.4.2.1 Initiate mandated period of care

Figure 12 illustrates the use case diagrammatically, followed by description in Table 1, 2 and 3.

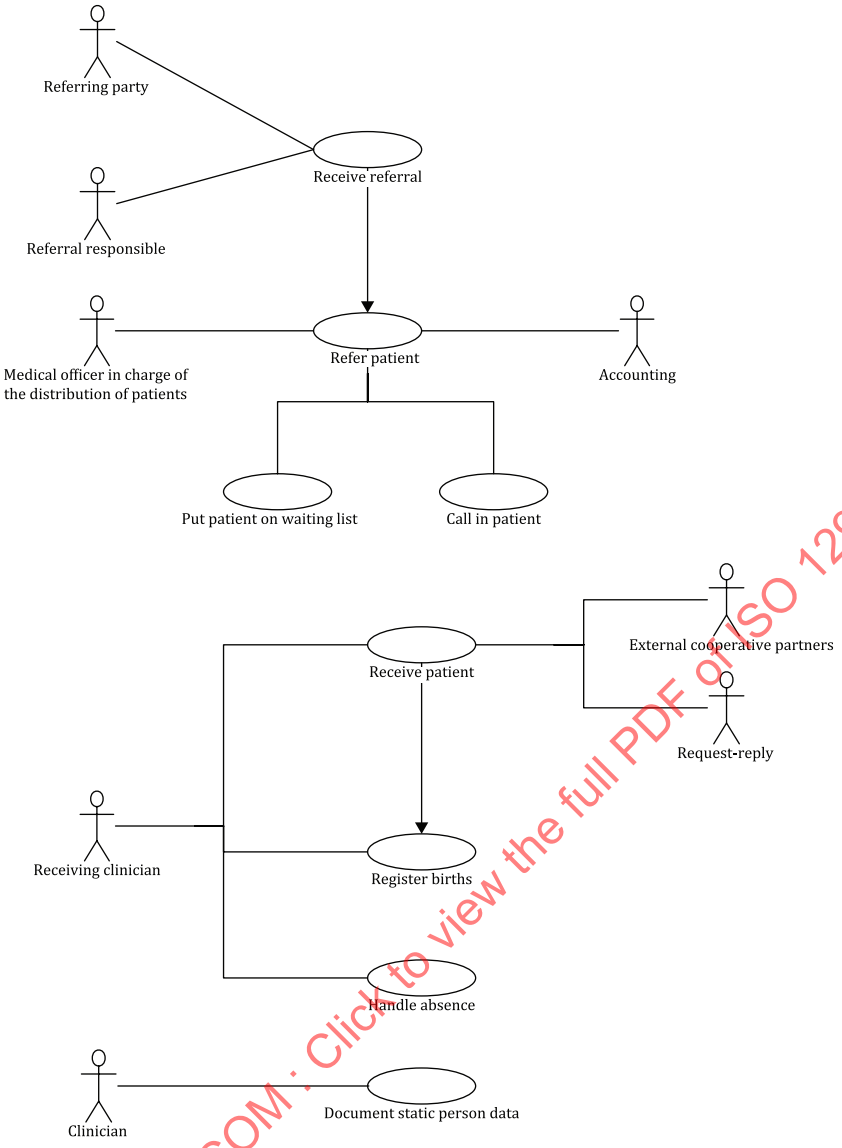


Figure 12 — Initiate mandated period of care: use-case diagram

Table 1 — Receive referral use case

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)	

Table 1 *(continued)*

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 mandated 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 case 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 send
Medical officer in charge of the distribution of patients has been notified and has taken over the responsibility

Table 2 — Call in patient use case

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

Table 3 — Receive patient use case

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 mandated period of care. For example: The patient is received in the emergency unit, then the acute receival unit, then a clinical department, then the outpatient clinic. For example: The patient arrives the first time in the outpatient clinic, then the clinical department for admission, then the outpatient clinic. Depending on an acute or planned mandated period of care, the available information (diagnosis, plan for mandated 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 organizational unit/hospital Examples – planned: Referred patient arrives in the outpatient 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 mandated period of care registrations are created	
Read healthcare record	
Register that the patient has arrived 4a. The patient arrives in the emergency unit or in an outpatient 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 an organizational unit different from the mandated period of care responsible 5b. Healthy companion	
Contact external cooperative partners (nursing home, home care, GP etc.)	
Request food and type of food	

Table 3 *(continued)*

Handle patient valuables
Start initial evaluation of the patient, including updating of person static data
Business rules All patients should 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 mandated period of care are able to see it

9.4.2.2 Examples of functions from ISO/HL7 10781 supporting the use case

The HL7 EHR System Functional Model provides a reference list of functions (ISO/HL7 10781:2015, Annex A) that may be present in an Electronic Health Record System (EHR-S) and defines a standardized model of the functions that may be present in EHR systems. The EHR-S Functional Model does not address whether the EHR-S is a system-of-systems or a single system providing the functions required by the users. The functions are defined by name, number and statement, supplemented with a description. Under each function, a number of individual (atomic) sub-functionalities are listed, having to be provided at differing levels of compliance. It is highly recommended that users of HISA refer to the HL7 EHR System Functional Model for functionalities to be provided by an EHR.

Examples of key functions supporting the above use case are given in Table 4 (referring to section, number, name and statement).

Table 4 — Key functions supporting the use case: initiate mandated period of care

Section	Number	Name	Statement
Care Provision Support	CPS.1.4	Capture Referral Request	Enable the receipt and processing of referrals from care providers or healthcare organizations, including clinical and administrative details of the referral, and consents and authorizations for disclosures as required.
Care Provision Support	CPS.4.6	Support for Referrals	Evaluate patient information for referral indicators.
Care Provision Support	CPS.4.6.1	Support for Referral Process	Evaluate referrals within the context of a patient's healthcare data.
Care Provision Support	CPS.4.6.3	Support for Electronic Referral Ordering	Enable the transmission of electronic referral orders from the EHR-S.
Care Provision	CP.4.6	Manage Orders for Referral	Enable the origination, documentation and tracking of referrals between care providers or healthcare organizations, including clinical and administrative details of the referral, and consents and authorizations for disclosures as required.
Care Provision Support	CPS.1	Record Management	Manage the patient record including all patient demographics, identifiers and other information to support the provision of care.
Care Provision Support	CPS.1.2	Manage Patient Demographics	Manage patient demographic information.

9.4.2.3 End period of care (diagram only)

Figure 13 illustrates the use case diagrammatically.

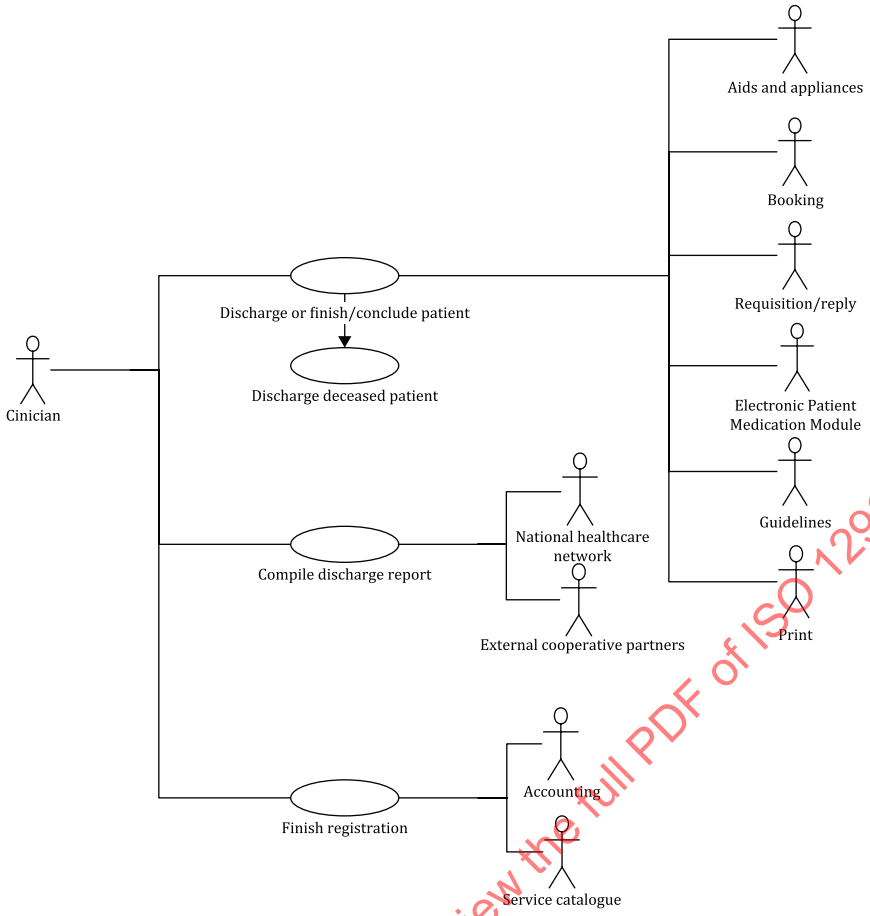


Figure 13 — End period of care: use-case diagram

9.4.2.4 Examples of functions from ISO/HL7 10781 supporting the use case

Example of a key function supporting the above use case is given in Table 5 (referring to section, number, name and statement).

Table 5 — Key function supporting the use case: end period of care

Section	Number	Name	Statement
Care Provision	CP9.1	Produce a Summary Record of Care	Render a summarized review of a patient's episodic, and/or comprehensive EHR, subject to jurisdictional laws and organizational policies related to privacy and confidentiality.

9.5 Healthcare information workflow

9.5.1 Textual specification of requirements

Healthcare information may be either elementary information or aggregations of multiple information on the patient, clustered on the basis of different criteria, depending both on the intrinsic characteristics of the healthcare information and also on the specific needs of the individual users. It is clear that, even if included in various structured health information, each piece of information shall 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 shall 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 healthcare information.

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

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

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

Most parts of the healthcare information available in the healthcare centre represent results of healthcare activities carried out by individual healthcare actors. It is stressed that creating direct explicit relationships between healthcare information and healthcare activities represents a major objective of the advanced 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 healthcare information 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 healthcare actions being executed.

Nevertheless, not all healthcare information is defined through a formalized healthcare activity directly carried out inside the individual centre or relevant enough to be explicitly planned and monitored in the organization. In fact, some healthcare information 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 healthcare information represents autonomous and self-consistent 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 healthcare information, instead of simply integrating such information as additional objects depending on the execution of healthcare activities.

9.5.2 Use-case examples

9.5.2.1 Diagnostic considerations and their documentation

Figure 14 illustrates the use case diagrammatically.

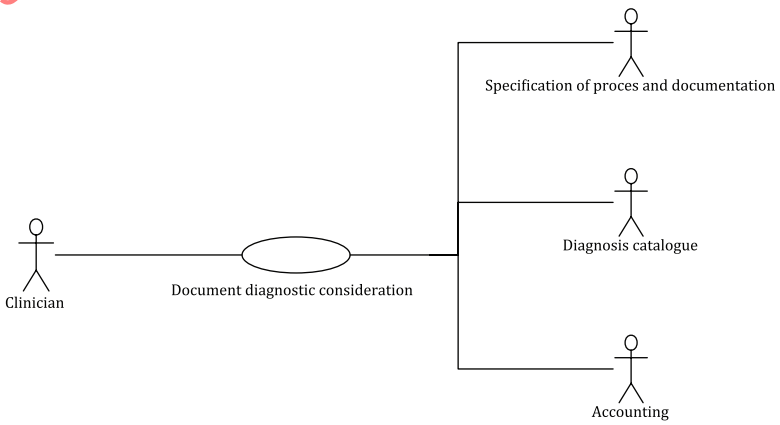


Figure 14 — Document diagnostic consideration

9.5.2.2 Examples of functions from ISO/HL7 10781 supporting the use case

Examples of key functions supporting the above use case are given in Table 6 (referring to section, number, name and statement).

Table 6 — Key functions supporting the use case: document diagnostic consideration

Section	Number	Name	Statement
Care Provision	CP.3	Manage Clinical Documentation	Clinical Documentation should be managed including the capture of the documentation during an encounter, maintenance and appropriate rendering.
Care Provision	CP.3.2	Manage Patient Clinical Measurements	Capture and manage patient clinical measures, such as vital signs, as discrete patient data.
Care Provision	CP.3.3	Manage Clinical Documents and Notes	Create, addend, amend, correct, authenticate, maintain, present and close, as needed, transcribed or directly-entered clinical documentation and notes.

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

Figure 15 illustrates the use case diagrammatically.

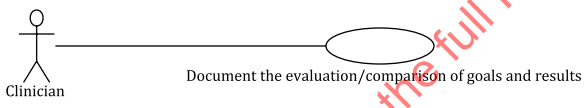


Figure 15 — Document for the evaluation/comparison of goals and results

9.6 Healthcare activity management workflow

9.6.1 Textual description of requirements

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

With respect to the complete set of requirements of the organization, the healthcare activities, directly or indirectly related to the needs of one patient and those which are carried out for organizational and administrative purposes, shall 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 information system, is the possibility of directly relating each healthcare activity to the needs of the individual patient.

The issues related to the management of the healthcare 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 information system, not only for improving the quality of the information services being provided, but also with respect to the related organizational, managerial and clinical issues.

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

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

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

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

From the moment when one healthcare 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 organisational units. A complete life cycle can therefore be modelled for the workflow connected to one healthcare activity, comprising a series of events and states through which the healthcare 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 healthcare actors may identify a set of healthcare activities to be actually performed either inside the same organizational unit or by other healthcare actors in different units of the organization. An actual healthcare activity is the instantiation of a certain type of healthcare activity, to be executed by one individual organizational unit for one specific situation, upon request of one specific requester.

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

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

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

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

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

— for each group of homogeneous healthcare activities, a formal requisition may be sent by the requester to the service point which is supposed to provide the healthcare activities. The request details the list of the healthcare activities which are requested, specifies the reasons for the requested healthcare activities and includes other possible administrative and healthcare information, depending on the organization and type of healthcare 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 healthcare 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 organizational unit, informing the original requester of the situation; such a process may be repeated several times, especially in the case of very complex healthcare activities;

— then the individual healthcare 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 healthcare 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 healthcare 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 healthcare activity is performed by the delivering healthcare actor;

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

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

— when all healthcare activities related to the delivery of the requested service by the providing organizational unit have been completed and a final report with the consolidated results of the healthcare activity has been finalized, the initial request can be considered to be completed and a formal communication is sent to the requester for acknowledgement hereof.

The different states of one healthcare act may be summarized in Table 7.

Table 7 — Basic states of one healthcare act

Foreseen	The healthcare activity to be done 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 organizational unit has formally accepted to provide the service.
Booked	The actual healthcare activities to be executed have been identified and a date, shift and time for execution has been agreed between the involved healthcare actors (i.e. requestor, provider and other involved organizational units).
Planned	The healthcare act has been assigned to one (set of) Service Point, which will be in charge for its execution.
Ready	All preliminary activities have been completed and the execution of the healthcare act may actually start
In progress	The execution of the healthcare act has actually started.
Completed	The provider has completed the actual execution of the healthcare act.
Reported	The provider has delivered the final report on the healthcare 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 healthcare act may also pass through the states in Table 8.

Table 8 — Further states of one healthcare act

Forwarded	The request of delivering the service has been transferred by the initially envisaged provider to a different provider.
Suspended	The processing of the healthcare act (in any moment of its life-cycle) has been temporary interrupted due to various reasons[a]
Annulled: Cancelled Rejected	One healthcare 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 healthcare 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 healthcare activity, various results may be generated, comprising coded information, textual information and other types of information. This information may be structured according to different criteria, depending on the characteristics of the healthcare activities and the specific healthcare actor's way of working. Depending on the type of healthcare activity which is being executed, such results may represent healthcare information of the patient, or just information of other type to be communicated in the healthcare organization.

When executing one healthcare 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 healthcare 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 information relevant for the healthcare organization as a whole. In fact, such 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 healthcare activity being performed in the organization and relevant to more than one application, representing a vital basis for supporting both the healthcare 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 healthcare activities will not be the responsibility of such 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

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

Figure 16 illustrates the use case diagrammatically, followed by description in Table 9.

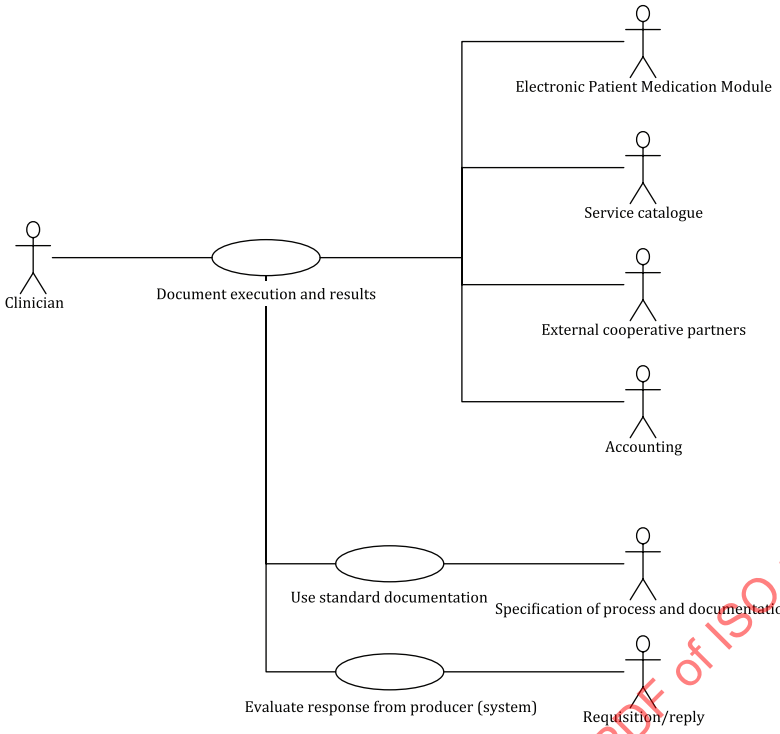


Figure 16 — Use-case diagram regarding execution of healthcare activities and documentation of results

Table 9 — Document execution and results, use case

Use case name: Document execution and results
Purpose and scope This use case describes tasks regarding execution and documentation of planned and non-planned healthcare activities. In regard to planned healthcare activities (activities created in the patients plan) the clinician should be supported in carrying them out. If a healthcare activity has not been planned, the clinician should be able to create and document the execution of the healthcare 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 healthcare activity, and, in some cases it will be enough to document the healthcare activity is executed, while other healthcare activities leads to a result (product). The content of the healthcare 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 healthcare activity results, where the necessary functionality to document the healthcare activity result, in principle, is the same. The clinician needs, for example, the same functionality for the healthcare activity results 'recorded patient history' and 'description of operation', such as word processing functionality, for which reason both healthcare activity results belong to the result archetype 'narrative documentation of activity result'. The optimal support for the workflow/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 can be handled by a 'module for process and documentation specification'.

Table 9 *(continued)*

Event
Execution and documentation of one or more planned healthcare activities
Execution and documentation of one or more acute healthcare 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 a healthcare activity to be executed/documented.
2a. Same healthcare activity should be executed for several patients
2b. Execute several healthcare activities for the same patient
2c. The healthcare activity is not created
Document the execution of a healthcare activity
Document execution and result using standard documentation
Document healthcare activity result in narrative text
Document healthcare activity results which leads to a diagnosis
Document numerical measurement results
Document healthcare activity results using a scale
8a. Binominal scale
8b. Nominal scale
8c. Rank scale
Document the healthcare activity result on a graphical scale
Document the healthcare activity result on a visual analogue scale
Document the healthcare activity result by digital images or video
Document the healthcare activity result by digital drawing
Document the healthcare activity result by digital sound
Document healthcare activity results which are available on paper
Compare the healthcare activity results with similar results in the patients record
15a. Show earlier healthcare activity results of the same type
15b. Show operational goal for the healthcare activity
Communicate matters regarding unfinished healthcare activity results and execution notes
16a. The healthcare activity has been executed, but not yet documented
16b. The result is a draft
Evaluate the healthcare activity result from a producer (system)
Document healthcare information which is not a result of an activity

Table 9 *(continued)*

Document an ongoing healthcare activity which is supposed to pause (typically healthcare activities regarding medication)
Document an aborted/interrupted healthcare activity
Use guidelines for documentation of the execution note or healthcare activity result 21a. Document handed out patient instruction
Document the same execution note or healthcare activity result for several patients
Handle accounting-related matters regarding healthcare activities
Print result 24a. Send the result electronically
Business rules
End results The healthcare activities are executed and documented The healthcare activity is aborted/interrupted and the reason is documented.

9.6.3 Examples of functions from ISO/HL7 10781 supporting the use case

Examples of key functions supporting the above use case are given in Table 10 (referring to section, number, name and statement).

Table 10 — Key functions supporting the use case: document execution and results

Section	Number	Name	Statement
Care Provision	CP.4	Manage Orders	Provide the ability to manage clinical orders and results including medication, non-medication, diagnostic tests, blood products, other biologics and referrals, using order sets as appropriate.
Care Provision	CP.4.2	Manage Medication Orders	Create prescriptions or other medication orders with detail adequate for correct filling and administration. Provide information regarding compliance of medication orders with formularies. Provide drug utilization review functionality including alerts regarding drug interactions and allergies.
Care Provision	CP.4.4	Manage Orders for Diagnostic/Screening Tests	Enable the origination, documentation, transmission, tracking and maintenance of orders for diagnostic tests.
Care Provision	CP.5	Manage Results	Present, annotate, and route current and historical test results to appropriate providers for review. Provide the ability to filter and compare results.
Care Provision	CP.5.1	Manage Results of Diagnostic Tests	Enable the receipt and display of results for diagnostics tests.
Care Provision Support	CPS.2.1	Support externally-sourced Clinical Documents	Incorporate clinical documentation (computable and scanned) from external (to the system) sources.
Care Provision Support	CPS.2.2	Support externally-sourced Clinical Data	Incorporate discrete clinical data from external sources and support communication/presentation of data captured from medical and non-medical devices and entities.

Table 10 *(continued)*

Section	Number	Name	Statement
Care Provision Support	CPS.4	Support Orders	Support for Orders is required to ensure that appropriate decision support and safety checks are conducted by the system at the time of ordering as well as at the time of dispensing medications or immunizations.
Care Provision Support	CPS.5	Support for Results	Evaluate results and notify provider and patient of results within the context of the patient's healthcare data.

9.7 Resources management activities

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 shall 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 quality and costs.

In addition, resources are not only relevant for the healthcare activities of the clinicians, 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 is involved in executing or contributing to certain work.

9.8 Management activities for users and authorizations

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 information;

— 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 information is 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 document and of this set of information services of the standard.

Apart from the need for ensuring the intrinsic security of the information, 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 a set of conditions, which describe its authorization in terms of information, such as:

— working ways, defining whether the profile is allowed to add new information or read, update, or delete existing information;

— 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 healthcare actor is allowed access;

— workstations, which specify a list of workstations or nodes of the information system from which the healthcare actor is allowed access.

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

Each healthcare actor of the information system can be characterized by a name, a unique public identifier, e.g. a code, and some mechanisms for ensuring correct identification. To access a component, the healthcare actor shall be a member of one authorization profile of that component. Such membership is granted by another individual healthcare actor, 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 healthcare actor, with respect to the standard authorizations defined for its profile. Also, such exceptions shall be defined by one individual healthcare actor and are described through a set of conditions.

9.9 Classifications, coding and dictionaries management activities

9.9.1 General 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 shall be integrated in one common enterprise information model. Through common facilities, it is also required for users 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 elements of the common, integrated, information model and the structure of messages and views required by specific healthcare information architectures and communication standards (e.g. HL7, CDA) 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 healthcare, 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 specific processes;

— at a global, enterprise level, the management of dependencies and relationships among different concepts for healthcare, 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 mandated period of care;

— class of healthcare information;

— class of healthcare activity;

— class of care 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 document 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 17.

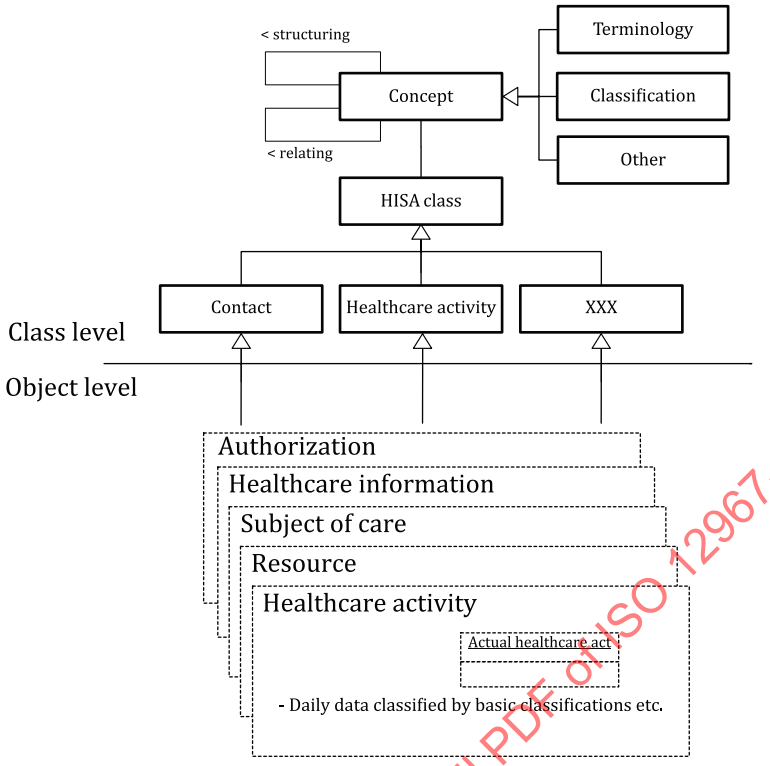


Figure 17 — The role of the classifications, coding and dictionaries management information services with respect to the other information services

9.9.2 Examples of functions from ISO/HL7 10781 providing support

Examples of key functions providing support are given in Table 11 (referring to section, number, name and statement).

Table 11 — Key functions supporting management of classifications, coding and dictionaries

Section	Number	Name	Statement
Trust Infrastructure	TI.4	Standard Terminology and Terminology Services	Support semantic interoperability through the use of standard terminologies, standard terminology models and standard terminology services.
Trust Infrastructure	TI.4.1	Standard Terminology and Terminology Models	Employ approved standard terminologies to ensure data correctness and to enable semantic interoperability (both within an enterprise and externally). Support a formal standard terminology model.
Trust Infrastructure	TI.4.3	Terminology Mapping	Map or translate one terminology to another as needed by local, regional, national, or international interoperability requirements.

Annex A
(informative)

Highlights of ODP

This document formalizes the architecture by using the methodology of ISO/IEC 10746 (all parts). 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 should 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 faces 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.