BS EN ISO 13940:2016

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Health informatics — System of concepts to support continuity of care

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National foreword

This British Standard is the UK implementation of EN ISO 13940:2016. It is identical to ISO 13940:2015. It supersedes BS EN 13940-1:2007 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

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

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European foreword

This document (EN ISO 13940:2016) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2016, and conflicting national standards shall be withdrawn at the latest by July 2016.

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Endorsement notice

The text of ISO 13940:2015 has been approved by CEN as EN ISO 13940:2016 without any modification.

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

0 Introduction

0.1 General

The purpose of this International Standard is to define the generic concepts needed to achieve continuity of care. Continuity of care is an important aspect of quality and safety in healthcare and semantic interoperability is a basic requirement for continuity of care. The concepts that are needed for these should represent both the content and context of the healthcare services.

Healthcare is provided through activities in healthcare and clinical processes. These types of processes reflect the interaction between a subject of care and healthcare professionals. A clinical process provides continuity from the subject of care's perspective. To complete the concepts representing continuity of care, a number of basic premises for management, resource handling and administration are also needed.

The system of concepts for continuity of care defined in this International Standard is based upon the clinical perspective with the clinical process as focus, it defines its component concepts and their descriptive terms regarding all types of healthcare and especially considering patient-centred continuity of care. This International Standard will establish a common conceptual framework across national, cultural and professional barriers.

0.2 Aims for this International Standard

The general aim for this International Standard is to provide a comprehensive, conceptual basis for content and context in healthcare services. It should be the foundation for interoperability at all levels in healthcare organizations and for development of information systems in healthcare.

The concepts aim to support the continuity of care in healthcare with clinical processes as the focus, enabling the use of healthcare information for other purposes such as secondary use for follow-up and knowledge management. The core business in healthcare is the interaction between subjects of care and healthcare professionals, such interactions occur in healthcare and clinical processes and are the justification for the process approach of this International Standard. To be able to represent both clinical content and clinical context, this International Standard is based upon the clinical perspective and has focus upon the clinical process as a main concept for achieving continuity of care.

To be able to support continuity of care, the standard also aims to include comprehensive concept definitions and concept relations for the clinical, management and resource aspects of healthcare.

In practice this International Standard aims to be used whenever requirements for information in healthcare are specified. This will cover all levels of specifications in the development of,

- enterprise models as a common basis for interoperability on international, national or local levels,
- information systems, and
- structured information for specified types of clinical processes.

0.3 About the concept of health

This International Standard is based on the World Health Organization's (WHO) declaration of health from 1948: "... a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". In 1986 WHO made two amendments to the above definition: "resource for everyday life, not the objective of living" and "health is a positive concept emphasizing social and personal resources, as well as physical capacities".

In the International Classification of Functioning, Disability and Health (ICF) of WHO, the concept of health is categorized in a more specified way. The theoretical model in ICF identifies health components; body function, body structure, activity and participation, personal and environmental factors respectively. This International Standard applies the ICF model of health based on the health declaration.

In this International Standard, the word “health” is not used as an isolated term designating any concept within the scope of the standard. The word “health” is merely used as prefix in several terms. The meaning of this prefix is that the concept represented by the term has to do with the subject of care’s health state or health condition, often in relation to a healthcare/clinical process.

0.4 Healthcare versus social care

Healthcare as well as social care has the objective to influence, restore and maintain health in the WHO sense. All kinds of activities that have the potential to influence any one of the five components of health mentioned in the ICF model can be a part of such care. There is an evident overlap between healthcare activities and social care activities. This International Standard is focused upon the part of healthcare that (in most cultures) does not include social care. The role of the subject of care is defined with respect to healthcare and the terms chosen are from this sector. However, many of the concepts are relevant for the social care sector and through the cooperation of the different domains of healthcare this International Standard should also be applicable for social care.

0.5 Intended users for this International Standard

All parties interested in the interoperability issues in health care are intended users of this health informatics standard. This includes, but is not limited to, healthcare professionals and teams, subjects of care, healthcare managers, healthcare funding organizations and all types of healthcare providers and community care teams.

This system of concepts is relevant across all healthcare information and the development and use of healthcare information systems. It can also be used for business analysis as a basis for organizational decisions and more widely in developments that are not inherently tied to the use of information systems.

0.6 Architecture of this system of concepts

To cover continuity of care, concepts are needed from all of these basic process aspects:

- Healthcare/clinical processes
- Management
- Support

This system of concepts is based upon the clinical perspective of healthcare, this being the healthcare/clinical processes. All other areas of work in healthcare both relate to and interact with the healthcare/clinical processes. As such, the management aspects of healthcare are identified in the process management areas and similarly the resource support areas are correspondingly identified as outcomes of the support processes. This architecture with the areas around the healthcare/clinical process is described in Figure 1.

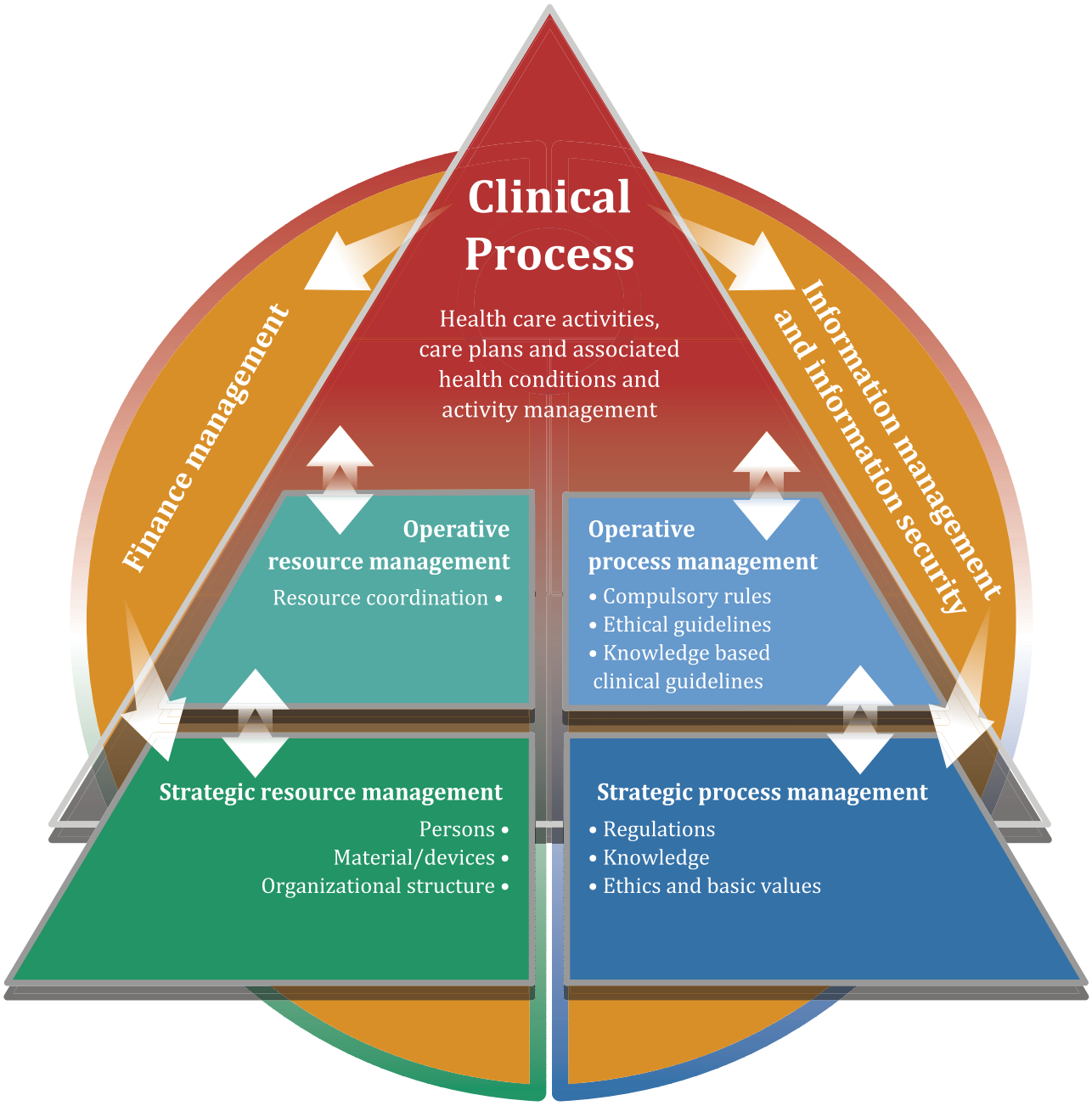

Figure 1 — Architecture of the concept areas

0.7 Description and display of concepts

In this International Standard the concepts are grouped into separate clauses. The relationships between the enterprise/information areas that need to be covered are used to structure this International Standard. Each of the concepts are defined and described systematically and their relations are shown in UML models.

Descriptions are framed within tables, following the same pattern, and information is systematically provided for all the concepts presented in Clauses 5 to 12. Some categories will intentionally be left blank as these are not relevant to a given concept.

Examples are provided wherever they are considered relevant and necessary. However and in general, examples for superordinate concepts are to be sought at the level of the corresponding subordinate concepts.

In order to help the reader understand the relationships between these concepts more easily, diagrams have been included based on UML conventions. For each one of the concepts described in Clauses 5 to 12, a partial view of the general subclause and comprehensive diagram is provided, showing only its direct relationships with other concepts belonging to the relevant aspect of the system of concepts.

At the beginning of Clauses 5 to 12 there are diagrams that provide partial views of the concepts that are to follow and focus upon the topic addressed in the corresponding clause. For clarity of reading,

- concepts shown in white with a solid border are defined in the same clause or subclause,
- concepts defined in other clauses or subclauses are shown in grey with a solid border,
- concepts not defined in this International Standard are shown in grey with a dashed border,
- for the concepts shown in white, all relationships are included,
- relationships between concepts shown in grey are not included,
- italic characters are used in the headings for concepts that are purely abstract and therefore supported only through their specializations.

The purpose of using concept models in this International Standard is to highlight the relationships between concepts. Attributes do not belong to the field of concept modelling. Attributes can be added in the course of implementation and still be conformant to this International Standard.

INTERNATIONAL STANDARD **ISO 13940:2015(E)**

Health informatics — System of concepts to support continuity of care

1 Scope

This International standard defines a system of concepts for different aspects of the provision of healthcare.

The core business in healthcare is the interaction between subjects of care and healthcare professionals. Such interactions occur in healthcare/clinical processes and are the justification for the process approach of this International Standard. To be able to represent both clinical content and clinical context, this International Standard is related to a generic healthcare/clinical process model as well as comprehensive concept definitions and concept models for the clinical, management and resource aspects of healthcare services.

In practice this International Standard covers the concept definitions needed whenever structured information in healthcare is specified as a requirement. The definitions are intended to refer to the conceptual level only and not to details of implementation. This International Standard will cover all levels of specifications in the development of

- logical reference models within the information viewpoint as a common basis for semantic interoperability on international, national or local levels,
- information systems, and
- information for specified types of clinical processes.

How to perform specific healthcare/clinical/informatics processes is not covered by this International Standard.

Healthcare research processes and healthcare educational processes are not covered in this International Standard.

2 Normative references

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

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and the following apply.

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/TR 18307:2001, 3.70, modified]

3.1.2
continuity of care
efficient, effective, ethical care delivered through interaction, integration, co-ordination and sharing of *information* (3.9.5) between different healthcare actors over time

Note 1 to entry: "Healthcare actors" is defined in 5.2.1.

3.2 Concepts and terms

3.2.1
concept
unit of knowledge created by a unique combination of characteristics

[SOURCE: ISO 1087-1:2000, 3.2.1]

3.2.2
system of concepts
DEPRECATED: concept system
set of *concepts* (3.2.1) structured according to the relations among them

[SOURCE: ISO 1087-1:2000, 3.2.11]

3.2.3
deprecated term
term rejected by an authoritative body

[SOURCE: ISO 1087-1:2000, 3.4.17]

3.3 Actors

3.3.1
organization
unique framework of authority within which a *person* (3.3.4) or persons act, or are designated to act towards some purpose

[SOURCE: ISO/IEC 6523-1:1998, 3.1]

Note 1 to entry: Groupings or subdivisions of organizations may also be considered as organizations where there is need to identify them in this way for purposes of information interchange.

Note 2 to entry: In this International Standard, this definition applies to any kind of organizations, whatever their legal status.

3.3.2
organizational pattern
relationships between the various parts of an *organization* (3.3.1)

3.3.3
party
person or group performing a *role* (3.3.5) in relation to the business of a specific community or domain

[SOURCE: ISO 8459:2009, 2.33]

3.3.4
person
human being regarded as an individual

3.3.5
role
function or position

[SOURCE: ISO/HL7 21731:2006]

3.3.6
person role
role (3.3.5) of a *person* (3.3.4)

3.3.7
organization role
role (3.3.5) of an *organization* (3.3.1)

3.4 Resources

3.4.1
resource
asset that is utilized or consumed during the execution of a *process* (3.6.1)

Note 1 to entry: Includes diverse entities such as funding, personnel, facilities, capital equipment, tools, and utilities such as power, water, fuel and communication infrastructures.

Note 2 to entry: Resources include those that are reusable, renewable or consumable.

EXAMPLE Time, personnel, human skills and knowledge, equipment, services, supplies, facilities, technology, data, money

[SOURCE: ISO/IEC/IEEE 15288:2015, 4.1.38, modified]

3.4.2
medical device
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing *information* (3.9.5) for medical purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Note 1 to entry: This definition has been developed by the Global Harmonization Task Force (GHTF)

Note 2 to entry: Products, which could be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

— aids for disabled/handicapped people,

— devices for the treatment/diagnosis of diseases and injuries in animals,

— accessories for medical devices (see Note 3),

— disinfection substances,

— devices incorporating animal and human tissues which can meet the requirements of the above definition but are subject to different controls.

Note 3 to entry: Accessories intended specifically by manufacturers to be used together with a "parent" medical device to enable that medical device to achieve its intended purpose, should be subject to this International Standard.

[SOURCE: ISO 14971:2007, 2.9]

3.4.3
medicinal product
any substance or combination of substances that can be administered to human beings for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct, or modify physiological functions

Note 1 to entry: A medicinal product may contain one or more manufactured items and one or more pharmaceutical products.

Note 2 to entry: In certain jurisdictions a Medicinal Product may also be defined as any substance or combination of substances which may be used to make a medical diagnosis.

Note 3 to entry: The provisions in this International Standard apply to proprietary medicinal products for human use intended to be placed on the market and to industrially manufactured medicinal products, the marketing of which has been authorized by a Medicines Regulatory Agency. However, the provisions do not apply to medicinal products prepared according to prescription, for instance, prepared in a pharmacy from a prescription intended for a specific patient; medicinal products prepared in accordance with an official formula, for instance, prepared in a pharmacy in accordance with the instructions in a pharmacopoeia and intended to be given direct to the patient by the pharmacy; medicinal products intended for research and development trials; intermediate products intended for subsequent processing by an authorized manufacturer.

[SOURCE: ISO 11615:2012, 3.1.49]

3.5 Management

3.5.1
quality in healthcare
degree to which *healthcare* (3.1.1) fulfils requirements related to defined quality characteristics

Note 1 to entry: Quality is defined in ISO 9000:2015, 3.6.2, as the 'degree to which a set of inherent characteristics of an object fulfils requirements'.

3.5.2
quality management
management with regard to quality

Note 1 to entry: Quality management can include establishing quality policies and quality objectives, and processes to achieve these quality objectives through quality planning, quality assurance, quality control, and quality improvement.

[SOURCE: ISO 9000:2015, 3.3.4]

3.5.3
quality assurance
part of *quality management* (3.5.2) focused on providing confidence that quality requirements will be fulfilled

[SOURCE: ISO 9000:2015, 3.3.6]

3.5.4
quality control
part of *quality management* (3.5.2) focused on fulfilling quality requirements

[SOURCE: ISO 9000:2015, 3.3.7]

3.5.5
risk
combination of the probability of an event and its consequences

[SOURCE: ISO Guide 73:2009, 1.1]

3.5.6
unintended event
phenomenon that is not part of the normal course of a *process* (3.6.1) but might influence it

Note 1 to entry: An unintended event can be either expected or unexpected.

Note 2 to entry: Activities in a process are deliberate and have a purpose. In an ideal situation purposes are always fulfilled. If an activity in whatever other process has an impact on the process currently analysed, the effect of this activity is perceived by the current process as an unintended event. Then the course of the process may deviate from the expected one. Such an exception from the desired course might prove negative or positive in comparison to the desired process outcome.

EXAMPLE Surgical complication (anatomy and tissue reacts in an unexpected manner), electrical failure, contamination in a medicinal product, hardware failure, spontaneous recovery when the patient is awaiting therapy.

3.6 Process management

3.6.1
process
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Whether the “intended result” of a process is called output, product or service depends on the context of the reference.

Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes.

Note 3 to entry: Two or more interrelated and interacting processes in series can also be referred to as a process.

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 validated is frequently referred to as a “special process”.

Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified to prevent circularity between process and output, and Notes 1 to 5 to entry have been added.

[SOURCE: ISO 9000:2015, 3.4.1]

3.6.2
process model
representation of a *process* (3.6.1)

3.6.3
product
output of an organization that can be produced without any transaction taking place between the organization and the customer

Note 1 to entry: Production of a product is achieved without any transaction necessarily taking place between provider and customer, but can often involve this service element upon its delivery to the customer.

Note 2 to entry: The dominant element of a product is that it is generally tangible.

Note 3 to entry: Hardware is tangible and its amount is a countable characteristic (e.g. tyres). Processed materials are tangible and their amount is a continuous characteristic (e.g. fuel and soft drinks). Hardware and processed materials are often referred to as goods. Software consists of information regardless of delivery medium (e.g. computer programme, mobile phone app, instruction manual, dictionary content, musical composition copyright, driver's license).

[SOURCE: ISO 9000:2015, 3.7.6]

3.6.4
service
output of an *organization* (3.3.1) with at least one activity necessarily performed between the organization and the customer

Note 1 to entry: The dominant elements of a service are generally intangible.

Note 2 to entry: Service often involves activities at the interface with the customer to establish customer requirements as well as upon delivery of the service and can involve a continuing relationship such as banks, accountancies or public organizations, e.g. schools or hospitals.

Note 3 to entry: Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible *product* (3.6.3) (e.g. a car to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of *information* (3.9.5) in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants);

Note 4 to entry: A service is generally experienced by the customer.

[SOURCE: ISO 9000:2015, 3.7.7]

3.6.5
output
result of a process

Note 1 to entry: Whether an output of the *organization* (3.3.1) is a *product* (3.6.3) or a *service* (3.6.4) depends on the preponderance of the characteristics involved, e.g. a painting for sale in a gallery is a product whereas supply of a commissioned painting is a service, a hamburger bought in a retail store is a product whereas receiving an order and serving a hamburger ordered in a restaurant is part of a service.

[SOURCE: ISO 9000:2015, 3.7.5]

3.7 Time

3.7.1
appointment
arrangement to meet someone at a particular time and place

3.8 Responsibility

3.8.1
commitment
action resulting in an obligation by one or more of the participants in the act to comply with a rule or perform a contract

Note 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.

[SOURCE: ISO 12967-1:2009, 3.6.2]

3.9 Information management

3.9.1
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/IEC 2382:2015, 2121272, modified]

3.9.2
data repository
an identifiable *data* (3.9.1) storage facility

Note 1 to entry: In ISO 10303-22:1998 this is the definition of repository.

3.9.3
healthcare data
data (3.9.1) produced during healthcare activities

Note 1 to entry: Healthcare activity is defined in 7.2.

3.9.4
healthcare information
information (3.9.5) about a *person* (3.3.4), relevant to his or her *healthcare* (3.1.1)

3.9.5
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/IEC 2382:2015, 2123204, modified]

3.9.6
information model
formal model of a bounded set of facts, concepts or instructions to meet a specified requirement

[SOURCE: ISO 10303-1:1994, 3.2.21]

3.9.7
electronic health record
repository of *information* (3.9.5) regarding the health of a subject of care in computer processable format

Note 1 to entry: Subject of care is defined in 5.2.1.

[SOURCE: ISO 13606-2:2008, 4.7, modified]

3.9.8
medium
material on which data is stored (e.g. a magnetic disk)

[SOURCE: ISO/IEC 14776-151:2010, 3.1.117, modified]

4 Symbols and abbreviations

The following abbreviations are used for the terms defined in this International Standard.

DRG	Diagnosis-Related Group
EHR	Electronic Health Record
ICF	The International Classification of Functioning, Disability and Health
GP	General Medical Practitioner
WHO	World Health Organization
UML	Unified Modelling Language

5 Concepts related to healthcare actors

5.1 General

A model showing the associations between concepts related to actors in continuity of care is shown in Figures 2 and 3. For further detail about the diagram notation, please refer to 0.7 in the Introduction.

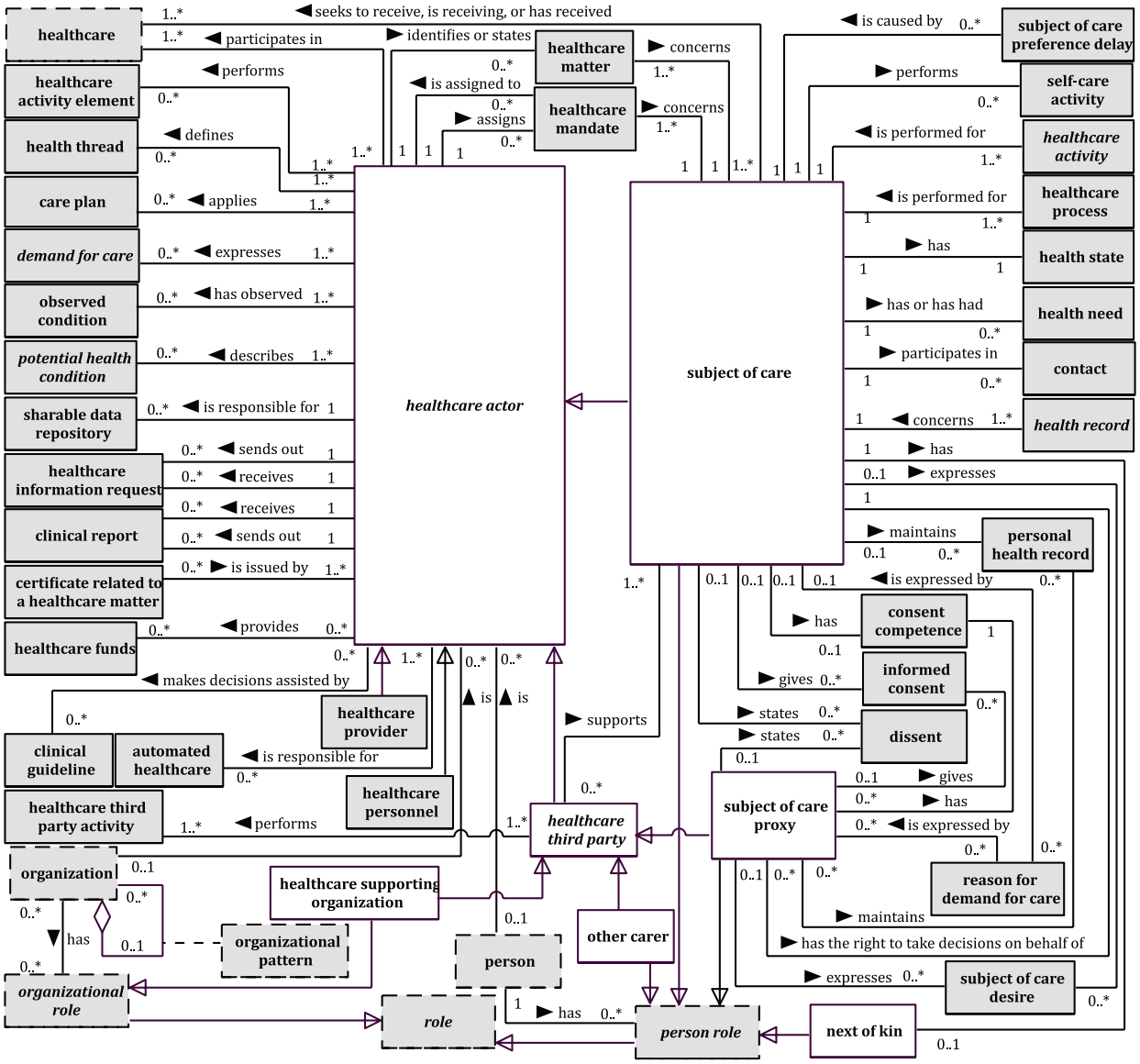

Figure 2 — Comprehensive UML diagram of concepts related to healthcare actors (i)

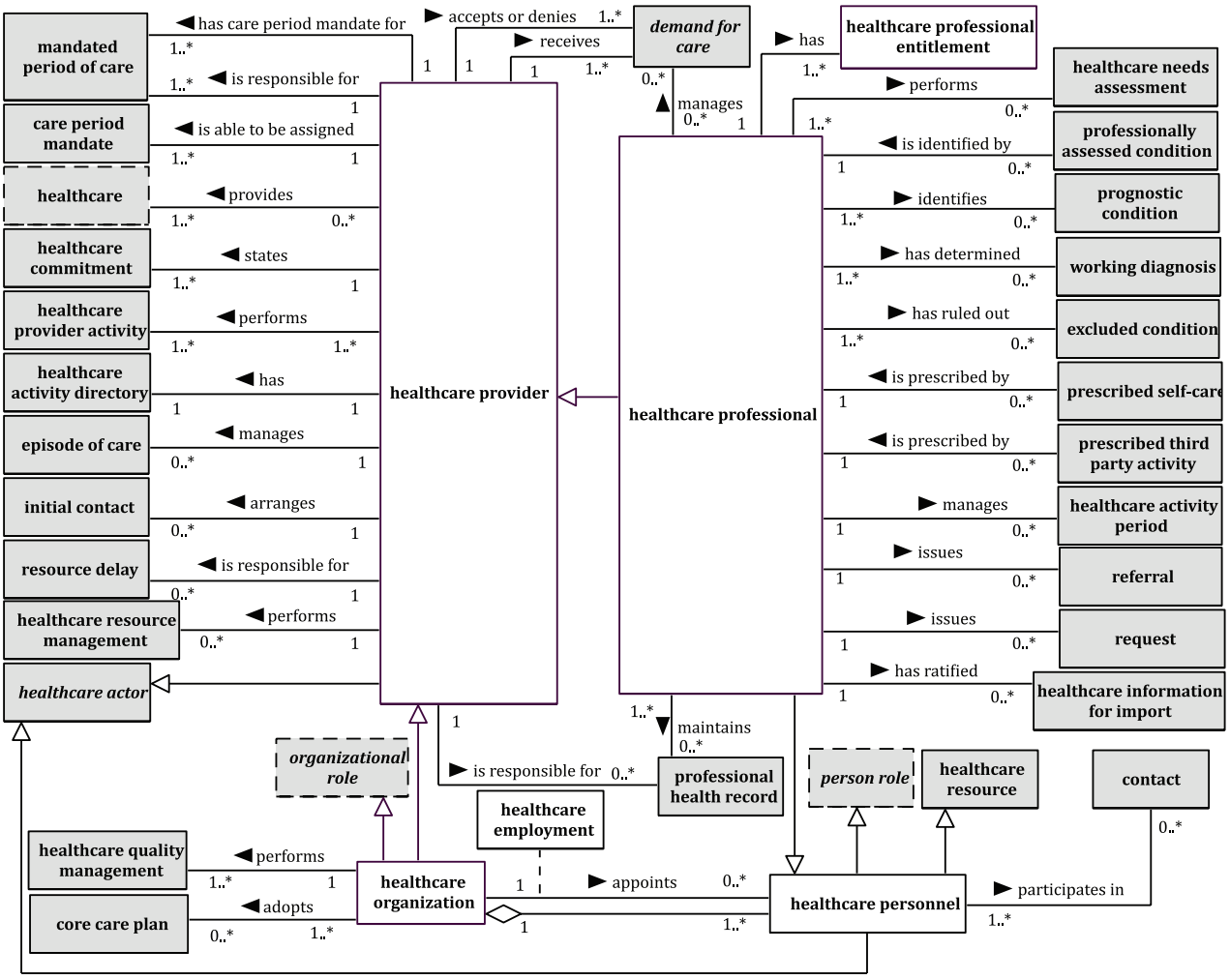

Figure 3 — Comprehensive UML diagram of concepts related to healthcare actors (ii)

5.2 Healthcare actor

Term: *healthcare actor*

Deprecated term: healthcare party

Definition: *organization* or *person* participating in *healthcare*

NOTE 1 The involvement of the *healthcare actor* will be either direct (for example, the actual provision of care), or indirect (for example, at organizational level).

NOTE 2 According to this definition, people or organizations responsible for the funding, payment, or reimbursement of healthcare provision are *healthcare actors*, as well as organizations responsible for healthcare delivery.

NOTE 3 In EN 13940–1:2007 healthcare party was the preferred term for this concept.

Table 1 lists the associations of this concept; a UML representation of the concept is shown in Figure 4.

Table 1 — Associations of *healthcare actor*

Specialization of	**Generalization of**
	healthcare provider
	subject of care
	healthcare personnel
	healthcare third party

Association from		**Association name**	**Association to**	
1..*	healthcare actor	participates in	1..*	healthcare
1	healthcare actor	identifies or states	0..*	healthcare matter
1..*	healthcare actor	defines	0..*	health thread
0..*	healthcare actor	makes decisions assisted by	0..*	clinical guideline
1..*	healthcare actor	applies	0..*	care plan
1	healthcare actor	is responsible for	0..*	sharable data repository
1..*	healthcare actor	expresses	0..*	demand for care
1	healthcare actor	sends out	0..*	healthcare information request
1	healthcare actor	receives	0..*	healthcare information request
1	healthcare actor	sends out	0..*	clinical report
1	healthcare actor	receives	0..*	clinical report
1..*	healthcare actor	performs	0..*	healthcare activity element
1..*	healthcare actor	is responsible for	0..*	automated healthcare
0..*	healthcare actor	provides	0..*	healthcare funds
1..*	healthcare actor	has observed	0..*	observed condition
1..*	healthcare actor	describes	0..*	potential health condition
1	healthcare actor	assigns	0..*	healthcare mandate
0..*	healthcare mandate	is assigned to	1	healthcare actor
0..1	person	is	0..*	healthcare actor
0..1	organization	is	0..*	healthcare actor
0..*	certificate related to a healthcare matter	is issued by	1..*	healthcare actor

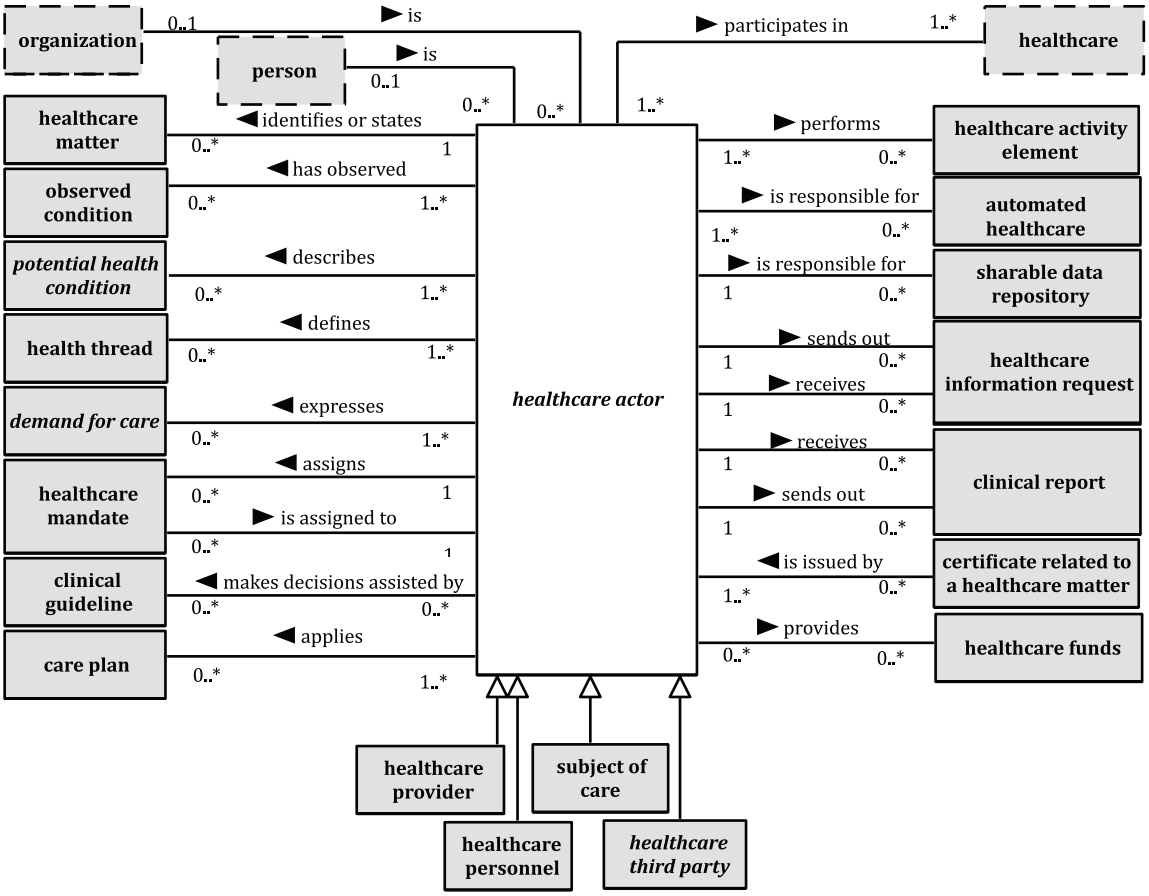

Figure 4 — Healthcare actor (UML representation)

5.2.1 Subject of care

Term: *subject of care*

Synonyms: subject of healthcare, patient, client, service user

Definition: *healthcare actor* with a *person role;* who seeks to receive, is receiving, or has received *healthcare*

NOTE A fœtus may be considered as a subject of care when receiving or when having received healthcare.

EXAMPLES A treated patient, a client of a physiotherapist, each particular member of a target population for screening, each particular member of a group of diabetic people attending a session of medical education, a person seeking health advice.

Table 2 lists the associations of this concept; a UML representation of the concept is shown in Figure 5.

Table 2 — Associations of *subject of care*

Specialization of	**Generalization of**
healthcare actor	
person role	

Association from		**Association name**	**Association to**	
1	subject of care	seeks to receive, is receiving, or has received	1..*	healthcare
1	subject of care	has	1	health state
1	subject of care	has or has had	0..*	health need
0..1	subject of care	maintains	0..*	personal health record
1	subject of care	performs	0..*	self-care activity
1	subject of care	has	0..*	next of kin
0..1	subject of care	has	0..1	consent competence
0..1	subject of care	expresses	0..*	subject of care desire
0..1	subject of care	gives	0..*	informed consent
0..1	subject of care	states	0..*	dissent
1	subject of care	participates in	0..*	contact
0..*	subject of care proxy	has the right to take decisions on behalf of	1	subject of care
0..*	subject of care preference delay	is caused by	1	subject of care
1..*	healthcare process	is performed for	1	subject of care
1..*	healthcare activity	is performed for	1	subject of care
1..*	healthcare matter	concerns	1	subject of care
1..*	healthcare mandate	concerns	1	subject of care
1..*	health record	concerns	1	subject of care
0..*	healthcare third party	supports	1..*	subject of care
0..*	reason for demand for care	is expressed by	0..1	subject of care

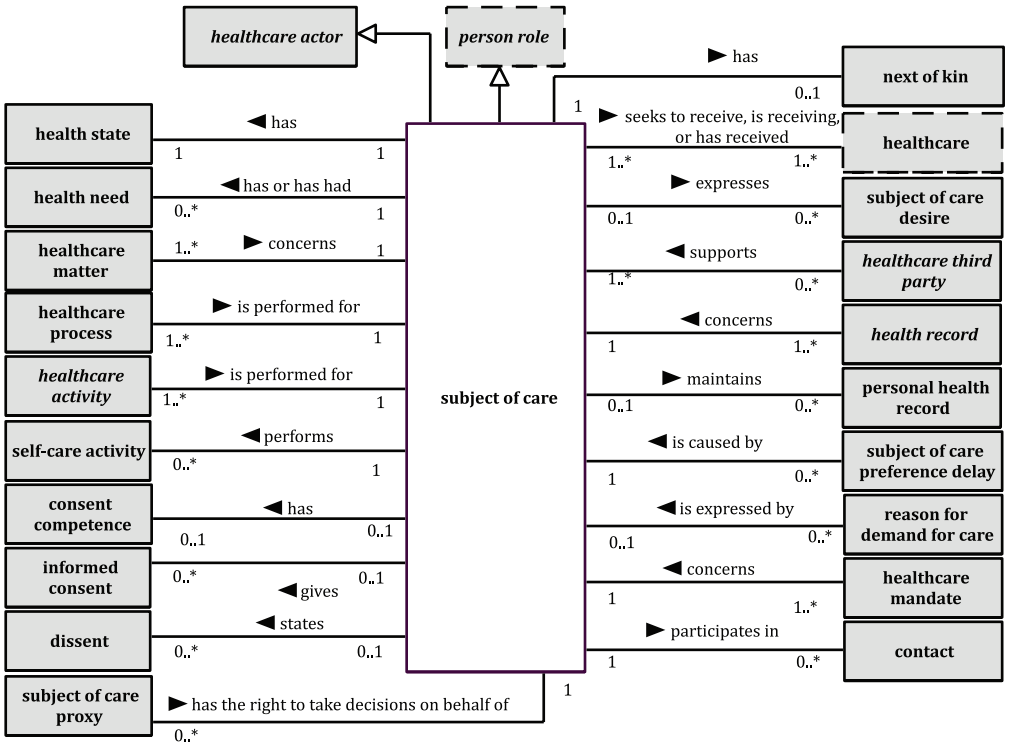

Figure 5 — Subject of care (UML representation)

5.2.2 Next of kin

Term: *next of kin*

Definition: *person role* being either the closest living relative of *the subject of care* or identified as the one he has a close relationship with

NOTE 1 The person that is the next of kin may participate implicitly or explicitly in healthcare by sometimes being a *subject of care proxy* when the *subject of care* has impaired consent competence. Thereby in these circumstances a person that is *next of kin* can perform the role of a *healthcare third party*.

NOTE 2 A person may play the role of *next of kin* to more than one *subject of care*

Table 3 lists the associations of this concept; a UML representation of the concept is shown in Figure 6.

Table 3 — Associations of *next of kin*

Specialization of		**Generalization of**			
person role					
Association from		**Association name**	**Association to**		
1	subject of care	has	0..1	next of kin	

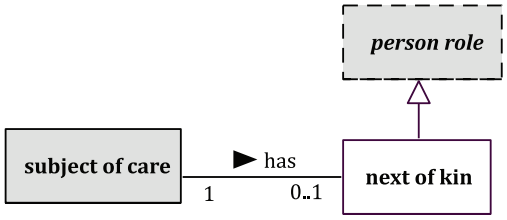

Figure 6 — Next of kin (UML representation)

5.2.3 Healthcare provider

Term: *healthcare provider*

Synonyms: care provider, health provider, health service provider, healthcare service provider

Definition: *healthcare actor* that is able to be assigned one or more *care period mandates*

NOTE 1 The personnel of a *healthcare organization* that is a *healthcare provider* may include both *healthcare professionals* and others which participate in the provision of healthcare.

NOTE 2 This International Standard includes only two specializations of *healthcare provider*. This is not meant to exclude the possibility of other specializations. In jurisdictions where other kinds of *healthcare actors* are included in the concept of *healthcare provider*, the necessary specializations may be added.

NOTE 3 According to this definition, organizations solely responsible for the funding, payment, or reimbursement of healthcare provision are not *healthcare providers*; for the purpose of this International Standard they are considered as *healthcare third parties*.

Table 4 lists the associations of this concept; a UML representation of the concept is shown in Figure 7.

Table 4 — Associations of *healthcare provider*

Specialization of	**Generalization of**
healthcare actor	healthcare organization
	healthcare professional

Association from		**Association name**	**Association to**	
0..*	healthcare provider	provides	1..*	healthcare
1	healthcare provider	has care period mandate for	1..*	mandated period of care
1	healthcare provider	is responsible for	1..*	mandated period of care
1..*	healthcare provider	performs	1..*	healthcare provider activity
1	healthcare provider	receives	1..*	demand for care
1	healthcare provider	accepts or denies	1..*	demand for care
1	healthcare provider	is responsible for	0..*	professional health record
1	healthcare provider	manages	0..*	episode of care
1	healthcare provider	is able to be assigned	1..*	care period mandate
1	healthcare provider	arranges	0..*	initial contact
1	healthcare provider	states	1..*	healthcare commitment
1	healthcare provider	has	1	healthcare activity directory
1	healthcare provider	is responsible for	0..*	resource delay
1	healthcare provider	performs	0..*	healthcare resource management

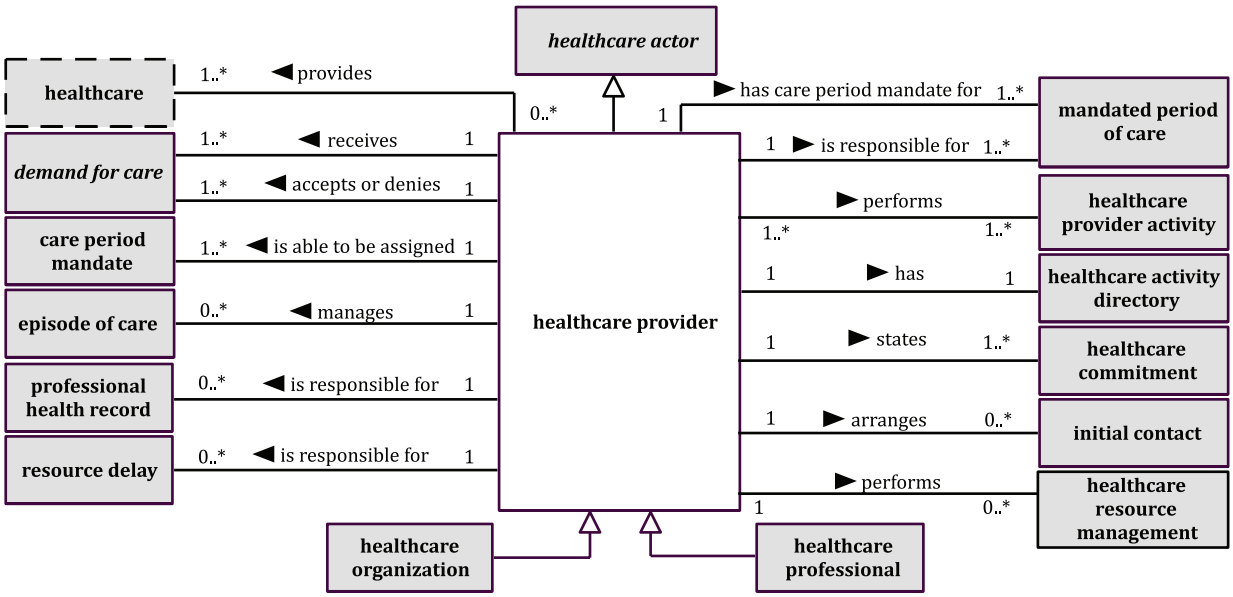

Figure 7 — Healthcare provider (UML representation)

5.2.3.1 Healthcare organization

Term: *healthcare organization*

Synonyms: care organization, healthcare delivery organization

Definition: *healthcare provider* having an *organization role*

NOTE 1 Groupings or subdivisions of an organization, such as departments or sub-departments, may also be considered as organizations where there is need to identify them. The internal structure of an organization is described by its organizational pattern. Therefore, an organization may be considered in itself as a standalone organization or as a superstructure containing departments and sub-departments, for instance, other lower level organizations. A *healthcare organization* represents the role any such organization plays when it is involved in the direct provision of *healthcare activities*.

NOTE 2 Effectively, a *healthcare organization* relies on the activity performed by healthcare personnel, whether employed, contracting, or with temporary informal though functional relationships between them. A healthcare team working together, for example, a specific type of *clinical process* with participants from different departments is also a kind of *healthcare organization*.

NOTE 3 A free-standing self-employed solo practising *healthcare professional* shall be considered as the only member of his/her own *healthcare organization*.

NOTE 4 Organizations may have a number of different roles. When an organization acts in a role where its *healthcare personnel* participate in the direct provision of healthcare, it is called a *healthcare organization*.

EXAMPLES A care team, a group practice, a hospital, a hospital department, a hospital care unit, self-employed GP

Table 5 lists the associations of this concept; a UML representation of the concept is shown in Figure 8.

Table 5 — Associations of *healthcare organization*

Specialization of	**Generalization of**
healthcare provider	

Table 5 *(continued)*

organizational role			
Component of		**Aggregation of**	
		1..*	healthcare personnel
Association from		**Association name**	**Association to**
1..*	healthcare organization	appoints	0..* healthcare personnel
1..*	healthcare organization	adopts	0..* core care plan
1	healthcare organization	performs	1..* healthcare quality management

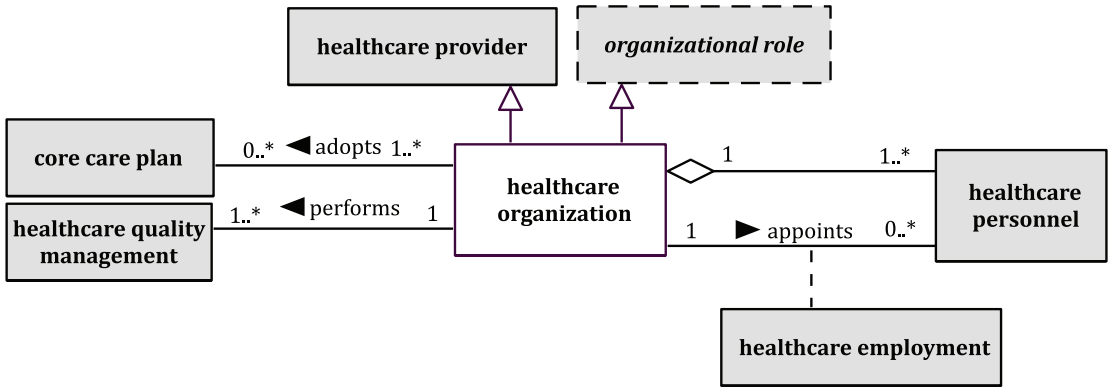

Figure 8 — Healthcare organization (UML representation)

5.2.3.2 Healthcare employment

Term: *healthcare employment*

Synonym: care employment

Definition: contractual framework between a *healthcare personnel* and a *healthcare organization* describing the roles and responsibilities assigned to that *healthcare personnel*

Table 6 lists the associations of this concept; a UML representation of the concept is shown in Figure 9.

Table 6 — Associations of *healthcare employment*

Association concept		**Links**			
1	healthcare employment	1	healthcare personnel	1	healthcare organization

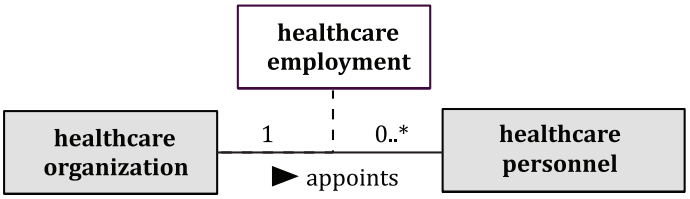

Figure 9 — Healthcare employment (UML representation)

5.2.3.3 Healthcare personnel

Term: *healthcare personnel*

Synonyms: care personnel, individual provider

Definition: individual *healthcare actor* having a *person role* in a *healthcare organization*

EXAMPLES GP, medical consultant, therapist, dentist, nurse, social worker, radiographer, nurse's assistant, children's nurse, nursing officer, head of department, social worker, medical consultant, etc.

Table 7 lists the associations of this concept; a UML representation of the concept is shown in Figure 10.

Table 7 — Associations of *healthcare personnel*

Specialization of			**Generalization of**		
healthcare actor			healthcare professional		
person role					
healthcare resource					
Component of			**Aggregation of**		
1	healthcare organization				
Association from		**Association name**	**Association to**		
1	healthcare organization	appoints	0..*	healthcare personnel	
1..*	healthcare personnel	participates in	0..*	contact	

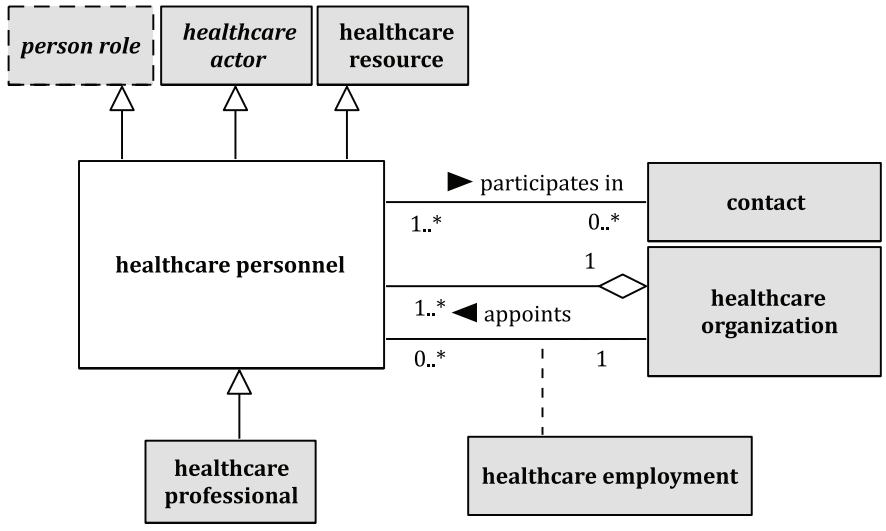

Figure 10 — Healthcare personnel (UML representation)

5.2.3.3.1 Healthcare professional

Term: *healthcare professional*

Synonym: care professional

Definition: *healthcare personnel* having *a healthcare professional entitlement* recognized in a given jurisdiction

NOTE The *healthcare professional entitlement* entitles a *healthcare professional* to provide healthcare independent of a role in a *healthcare organization*.

EXAMPLES GP, medical consultant, therapist, dentist, nurse, radiographer, etc.

Table 8 lists the associations of this concept; a UML representation of the concept is shown in Figure 11.

Table 8 — Associations of *healthcare professional*

Specialization of	**Generalization of**
healthcare provider	
healthcare personnel	

Association from		**Association name**	**Association to**	
1	healthcare professional	has	1..*	healthcare professional entitlement
1	healthcare professional	issues	0..*	referral
1	healthcare professional	issues	0..*	request
1	healthcare professional	manages	0..*	healthcare activity period
1..*	healthcare professional	maintains	0..*	professional health record
1	healthcare professional	has ratified	0..*	healthcare information for import
0..*	healthcare professional	manages	0..*	demand for care
1..*	healthcare professional	identifies	0..*	prognostic condition
1	healthcare professional	has determined	0..*	working diagnosis
1..*	healthcare professional	has ruled out	0..*	excluded condition
0..*	professionally assessed condition	is identified by	1	healthcare professional
0..*	prescribed self-care	is prescribed by	1	healthcare professional
0..*	prescribed third party activity	is prescribed by	1	healthcare professional
1..*	healthcare professional	performs	0..*	healthcare needs assessment

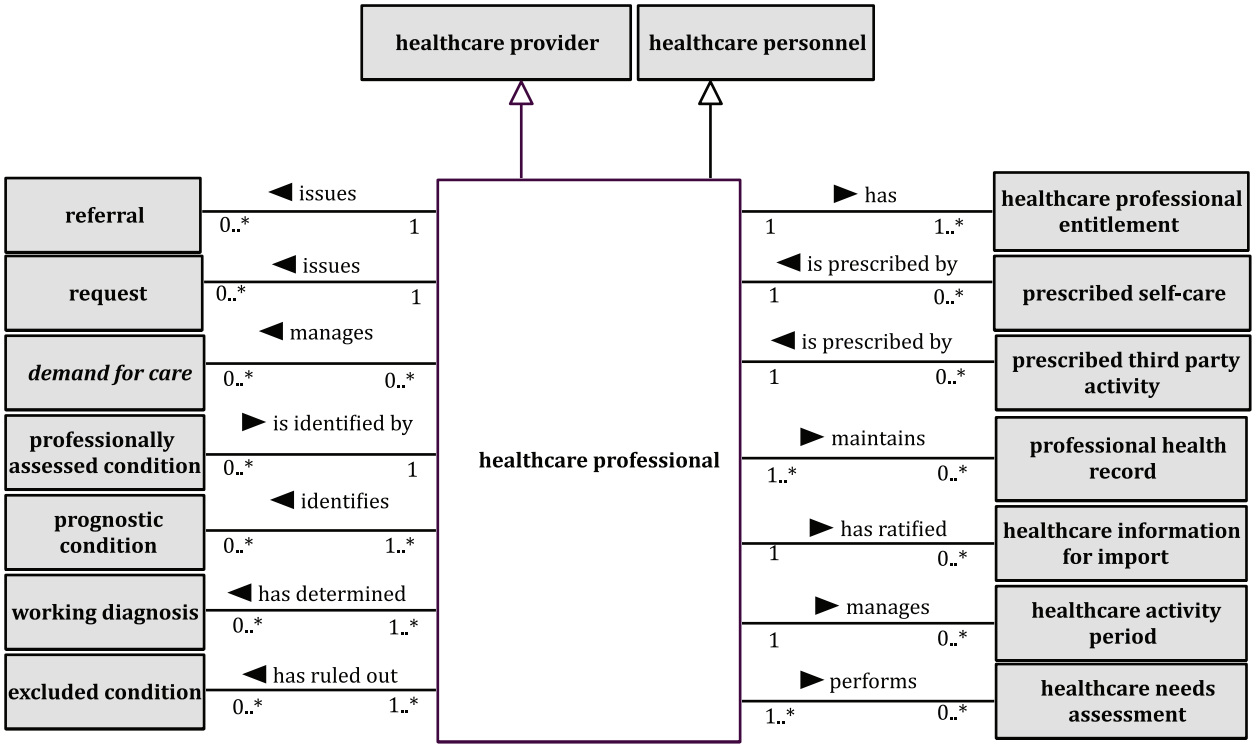

Figure 11 — Healthcare professional (UML representation)

5.2.3.3.2 Healthcare professional entitlement

Term: *healthcare professional entitlement*

Synonym: care professional entitlement

Definition: registered authorization given to a *person* in order to allow the *person* to have or perform specific roles in healthcare

NOTE 1 Entitlement is usually backed by evidence of having received, or continuously receiving, the necessary qualification, the relevant education and training.

NOTE 2 The official entitlement of a *healthcare professional* forms the foundation for his/her official duties and rights.

EXAMPLES Diploma, professional registration (e.g. registered nurse).

Table 9 lists the associations of this concept; a UML representation of the concept is shown in Figure 12.

Table 9 — Associations of *healthcare professional entitlement*

Association from		Association name	Association to	
1	healthcare professional	has	1..*	healthcare professional entitlement

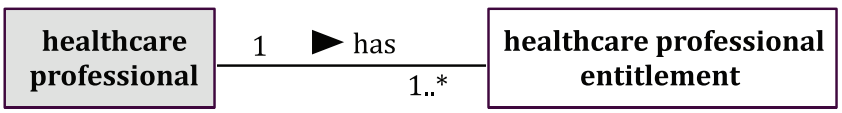

Figure 12 — Healthcare professional entitlement (UML representation)

5.2.4 Healthcare third party

Term: *healthcare third party*

Synonym: care third party

Definition: *healthcare actor* other than a *healthcare provider* or the *subject of care*

NOTE 1 According to this definition, a relative (family member) aiding the subject of care, any actor responsible for social support, or for the funding, payment, or reimbursement of healthcare provision are *healthcare third parties*.

NOTE 2 *Healthcare third party* is an abstract superordinate generic concept which is only fully supported through the use of one of its subordinate specific concepts.

Table 10 lists the associations of this concept; a UML representation of the concept is shown in Figure 13.

Table 10 — Associations of *healthcare third party*

Specialization of	**Generalization of**
healthcare actor	other carer
	subject of care proxy
	healthcare supporting organization

Association from		**Association name**	**Association to**	
0..*	healthcare third party	supports	1..*	subject of care
1..*	healthcare third party	performs	1..*	healthcare third party activity

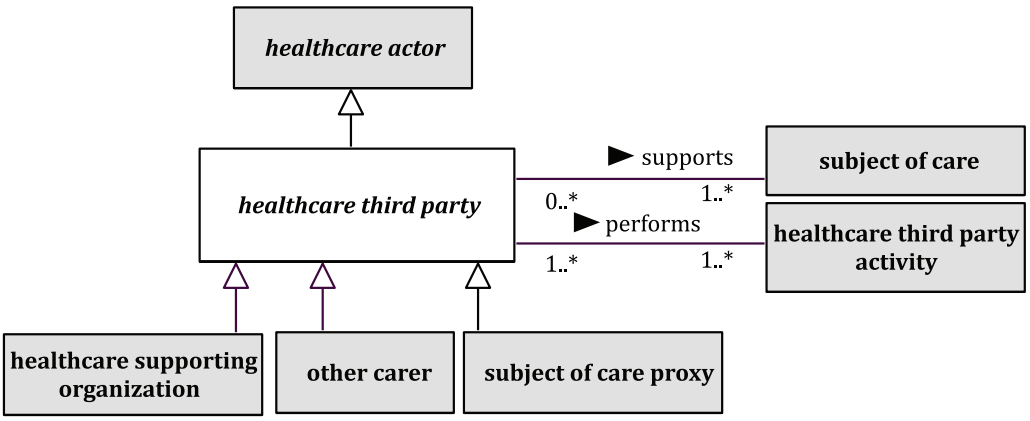

Figure 13 — Healthcare third party (UML representation)

5.2.4.1 Other carer

Term: *other carer*

Synonym: informal carer

Definition: *healthcare third party* having *person role*

EXAMPLES A relative (family member), a neighbour.

Table 11 lists the associations of this concept; a UML representation of the concept is shown in Figure 14.

Table 11 — Associations of *other carer*

Specialization of	Generalization of
healthcare third party	
person role	

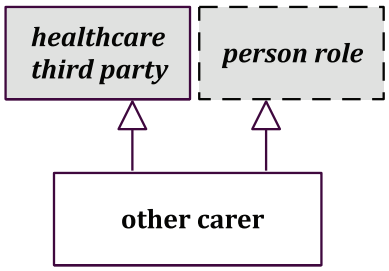

Figure 14 — Other carer (UML representation)

5.2.4.2 Healthcare supporting organization

Term: *healthcare supporting organization*

Synonym: care supporting organization

Definition: *healthcare third party* having *organizational role*

EXAMPLES Voluntary aid organization, a homecare service organization, a health insurance fund, the operator of a telemedicine system, family.

Table 12 lists the associations of this concept; a UML representation of the concept is shown in Figure 15.

Table 12 — Associations of *healthcare supporting organization*

Specialization of	Generalization of
healthcare third party	
organizational role	

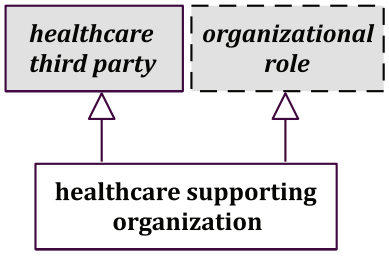

Figure 15 — Healthcare supporting organization (UML representation)

5.2.4.3 Subject of care proxy

Term: *subject of care proxy*

Synonym: subject of care agent

Definition: *healthcare third party* having *person role* with the right to take decisions on behalf of the *subject of care*

NOTE In ISO/TS 21298 subject of care agent is the preferred term for this concept.

Table 13 lists the associations of this concept; a UML representation of the concept is shown in Figure 16.

Table 13 — Associations of *subject of care proxy*

Specialization of	**Generalization of**
person role	
healthcare third party	

Association from		**Association name**	**Association to**	
0..1	subject of care proxy	gives	0..*	informed consent
0..*	subject of care proxy	has the right to take decisions on behalf of	1	subject of care
0..1	subject of care proxy	states	0..*	dissent
0..*	subject of care proxy	has	1	consent competence
0..*	reason for demand for care	is expressed by	0..*	subject of care proxy
0..*	subject of care proxy	maintains	0..*	personal health record
0..1	subject of care proxy	expresses	0..*	subject of care desire

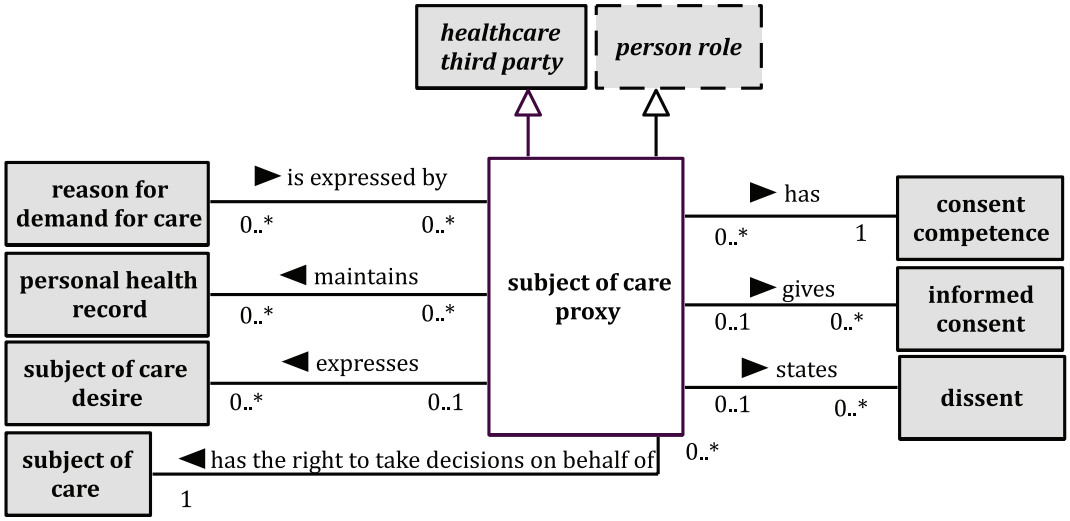

Figure 16 — Subject of care proxy (UML representation)

6 Concepts related to healthcare matters

6.1 General

A model showing the associations between concepts related to healthcare matters and the other concepts defined in this International Standard is shown in Figures 17 and 18. For further detail about the diagram notation, please refer to 0.7 in the Introduction.

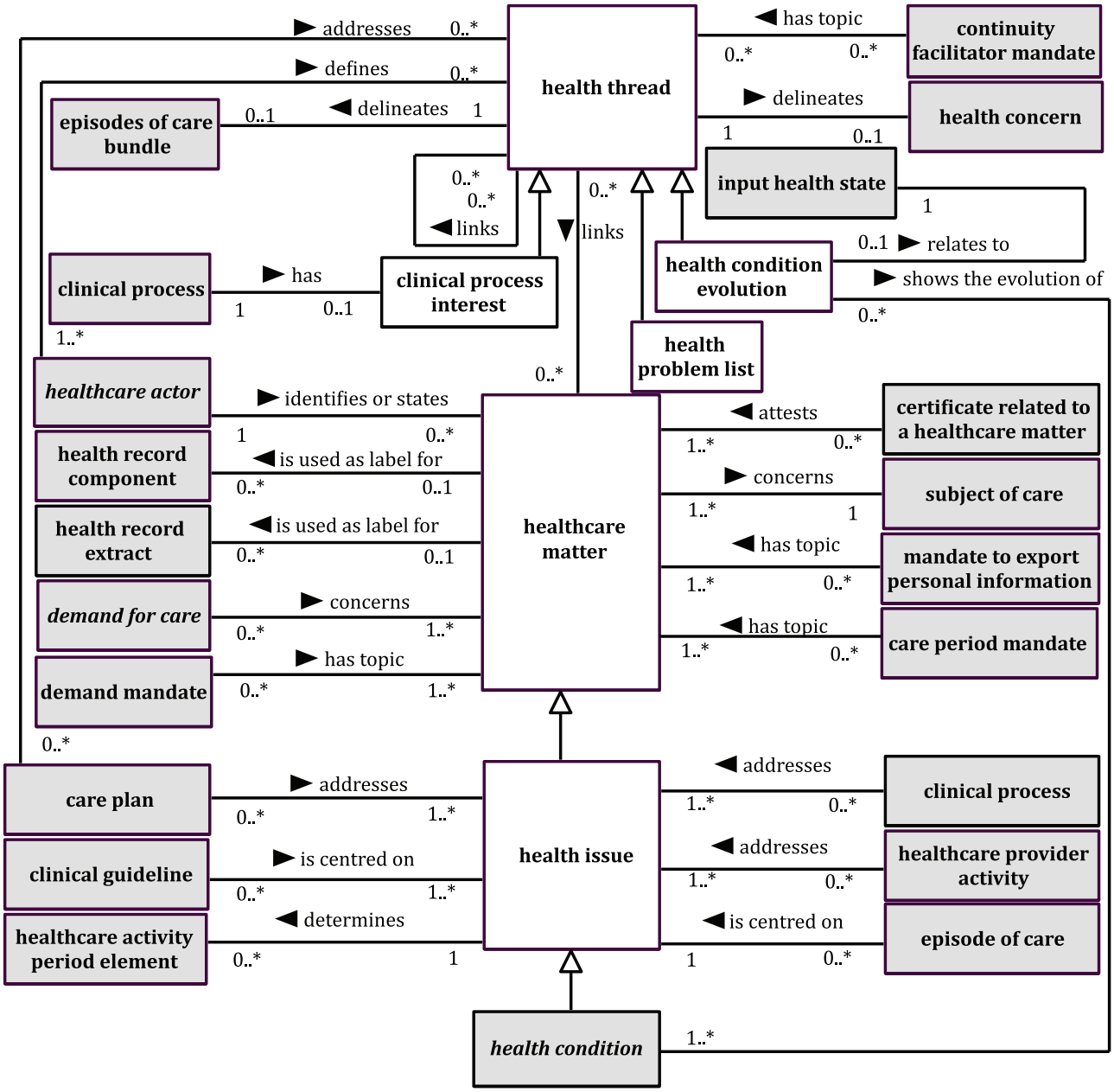

Figure 17 — Comprehensive UML diagram of concepts related to healthcare matters (i)

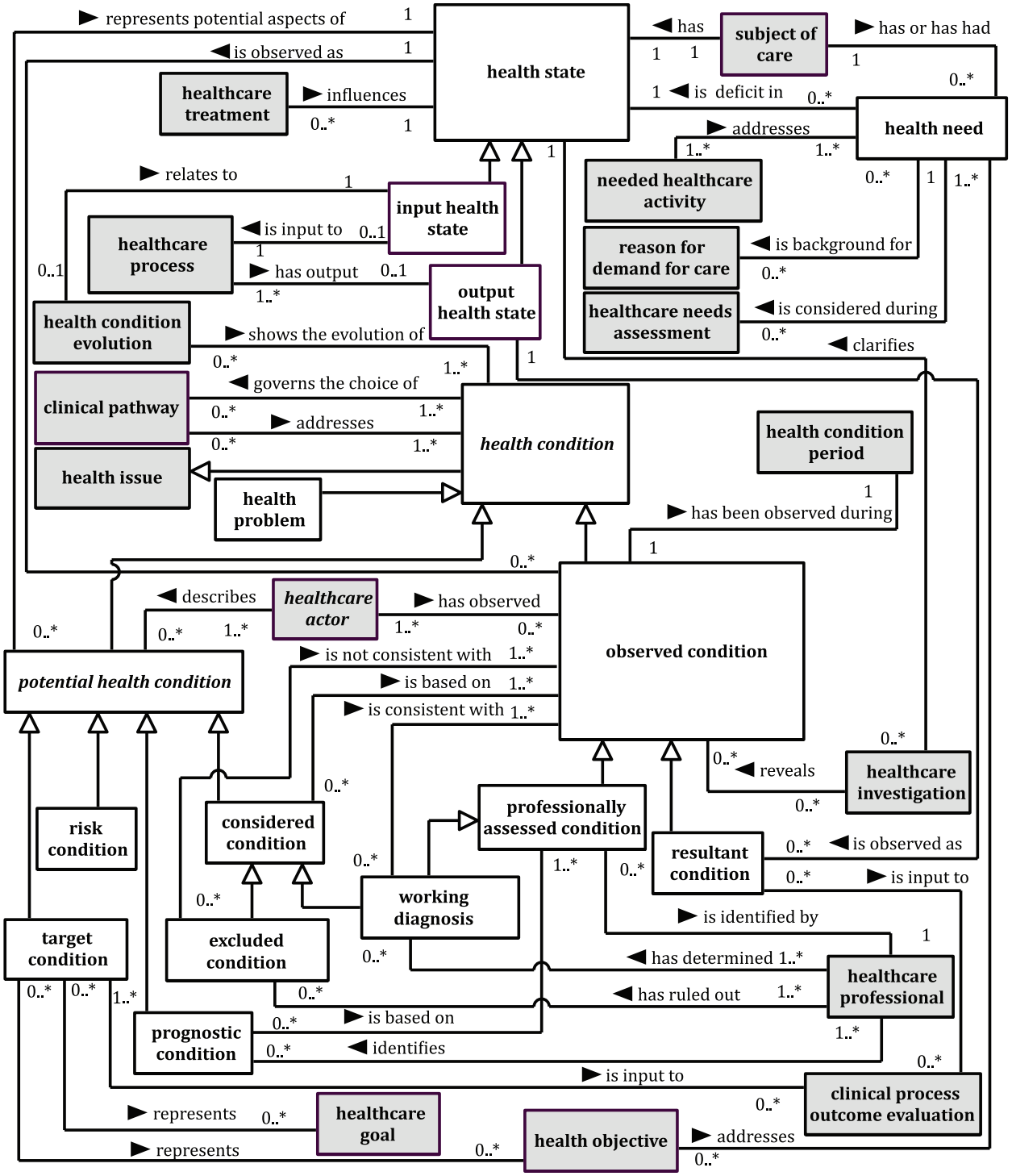

Figure 18 — Comprehensive UML diagram of concepts related to healthcare matters (ii)

6.2 Healthcare matter

Term: *healthcare matter*

Synonym: care matter

Definition: 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*

NOTE 1 *Healthcare matter* is a very broad and flexible concept that includes anything related to the health or the healthcare of a *subject of care*. This means that *health conditions*, *healthcare activities*, *health problems*, the result of *healthcare activities,* etc. all are possible to be identified as *healthcare matters*. Thereby *healthcare matter* might have several specializations and further associations.

NOTE 2 According to this definition, a *healthcare matter* can represent a disease, an illness or another kind of *health condition*. In addition a *healthcare matter* may represent, for example, a request for a procedure (therapeutic or preventive) by the subject of care or another *healthcare actor*.

NOTE 3 Concepts described and/or identified in a clinical terminology may represent types of *healthcare matter*.

NOTE 4 Other specializations of this concept than those included in this International Standard, may be created when needed.

EXAMPLES A loss of weight, an immunization, a heart attack, a drug addiction, a case of meningitis in the school, a water fluoridation, a health certificate, an injury, dermatitis, an X-ray investigation, an arthroscopy, an administration of an oral antibiotic, a post-operative infection.

Table 14 lists the associations of this concept; a UML representation of the concept is shown in Figure 19.

Table 14 — Associations of *healthcare matter*

Specialization of	**Generalization of**
	health issue

Association from		**Association name**	**Association to**	
1..*	healthcare matter	concerns	1	subject of care
0..1	healthcare matter	is used as label for	0..*	health record component
0..1	healthcare matter	is used as label for	0..*	health record extract
1	healthcare actor	identifies or states	0..*	healthcare matter
0..*	demand mandate	has topic	1..*	healthcare matter
0..*	care period mandate	has topic	1..*	healthcare matter
0..*	demand for care	concerns	1..*	healthcare matter
0..*	mandate to export personal information	has topic	1..*	healthcare matter
0..*	health thread	links	0..*	healthcare matter
0..*	certificate related to a healthcare matter	attests	1..*	healthcare matter

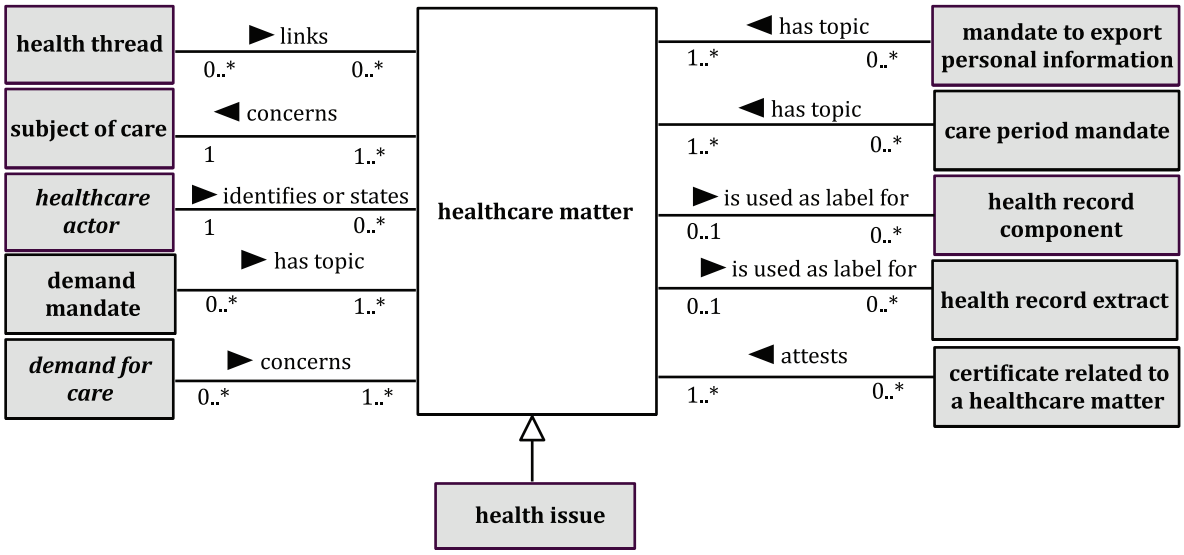

Figure 19 — Healthcare matter (UML representation)

6.3 Health issue

Term: *health issue*

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

NOTE According to this definition, a *health issue* can correspond to a health problem, a disease, an illness or another kind of *health condition*.

EXAMPLES A loss of weight, a heart attack, a drug addiction, an injury, dermatitis.

Table 15 lists the associations of this concept; a UML representation of the concept is shown in Figure 20.

Table 15 — Associations of *health issue*

Specialization of		**Generalization of**		
healthcare matter		health condition		
Association from		**Association name**	**Association to**	
1	health issue	determines	0..*	healthcare activity period element
0..*	clinical process	addresses	1..*	health issue
0..*	care plan	addresses	1..*	health issue
0..*	episode of care	is centred on	1	health issue
0..*	healthcare provider activity	addresses	1..*	health issue
0..*	clinical guideline	is centred on	1..*	health issue

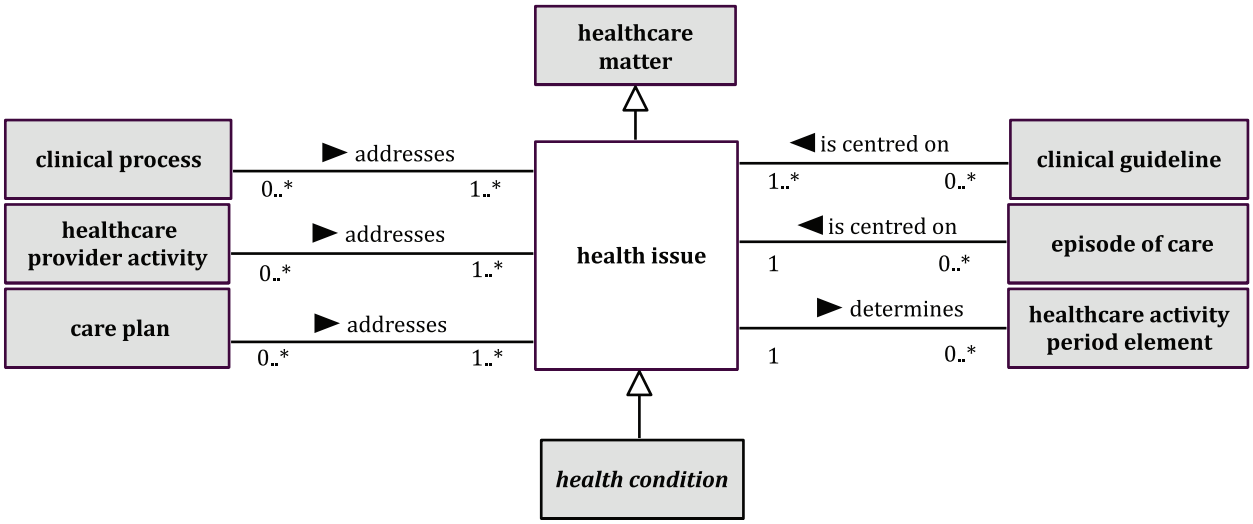

Figure 20 — Health issue (UML representation)

6.4 Health condition

Term: *health condition*

Definition: observed or potential observable aspects of the *health state* at a given time

NOTE 1 In the perspective of healthcare, the term *health condition* is often used to label a harmful or adverse condition (diseases, disorders, injuries, etc.), because it may motivate certain *healthcare activities*.

NOTE 2 A *health state* is an object, a perception of which is a *health condition*. The underlying *health state* is nevertheless present even if not perceived by an observer, for example, the *subject of care* having a cancer before it gives symptoms.

NOTE 3 In a *clinical process*, the *health state* of the *subject of care* is process input and also the process output. The evolving *health state* follows a life cycle and along its successive steps, is observed as different *health conditions*: initial, *observed condition*, *considered condition*, *professionally assessed condition*, *resultant condition* (the outcome of the process), evaluated.

NOTE 4 A diagnosis is a way to describe and label certain types of *health conditions*.

NOTE 5 *Health condition* may relate to a past, present or potential future *health state*.

NOTE 6 A *health condition* is a *health issue* and as such is a representation of aspect(s) of the *health state*.

EXAMPLES A *health problem*, diagnosis: an acute myocardial infarction (*professionally assessed condition*); a symptom: a head ache (*observed condition*).

Table 16 lists the associations of this concept; a UML representation of the concept is shown in Figure 21.

Table 16 — Associations of *health condition*

Specialization of		**Generalization of**		
health issue		observed condition		
		potential health condition		
		health problem		
Association from		**Association name**	**Association to**	
1..*	health condition	governs the choice of	0..*	clinical pathway

Table 16 *(continued)*

0..*	health condition evolution	shows the evolution of	1..*	health condition
0..*	clinical pathway	addresses	1..*	health condition

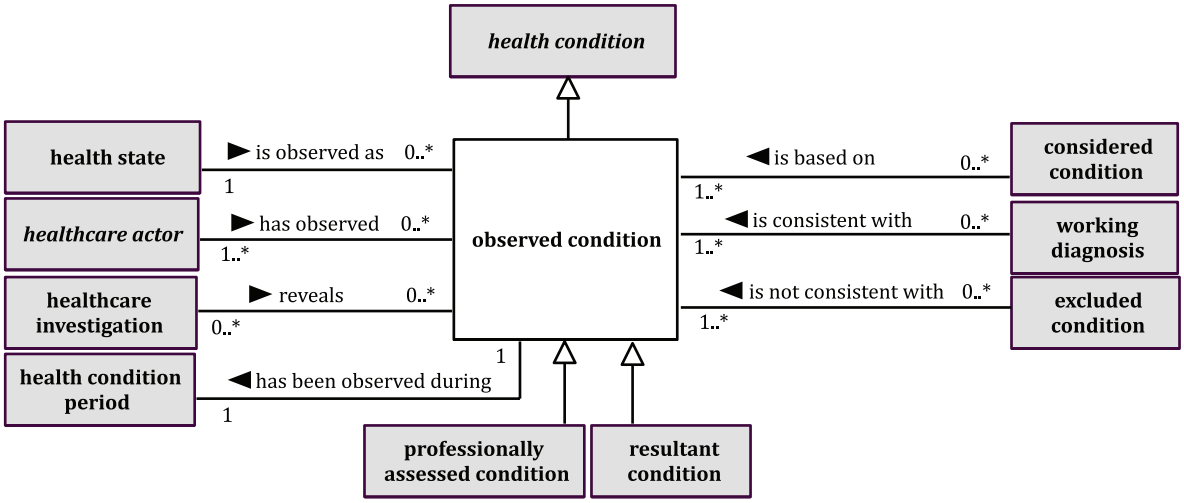

Figure 21 — Health condition (UML representation)

6.4.1 Observed condition

Term: *observed condition*

Synonym: observed health condition

Definition: *health condition* observed by a *healthcare actor*

NOTE 1 *Healthcare professionals* and *subjects of care* are examples of *healthcare actors* that can perceive the observed aspect of a health state.

NOTE 2 An *observed condition* is a *health issue* and as such is a representation of aspect(s) of the *health state*.

EXAMPLES A blood pressure, a swelling in the abdomen, tachycardia, body weight, lung infiltration on X-ray, a haemoglobin value, pale skin.

Table 17 lists the associations of this concept; a UML representation of the concept is shown in Figure 22.

Table 17 — Associations of *observed condition*

Specialization of	**Generalization of**
health condition	professionally assessed condition
	resultant condition

Association from		**Association name**	**Association to**	
1	health state	is observed as	0..*	observed condition
1	observed condition	has been observed during	1	health condition period
0..*	considered condition	is based on	1..*	observed condition
0..*	healthcare investigation	reveals	0..*	observed condition
1..*	healthcare actor	has observed	0..*	observed condition

Table 17 *(continued)*

0..*	working diagnosis	is consistent with	1..*	observed condition
0..*	excluded condition	is not consistent with	1..*	observed condition

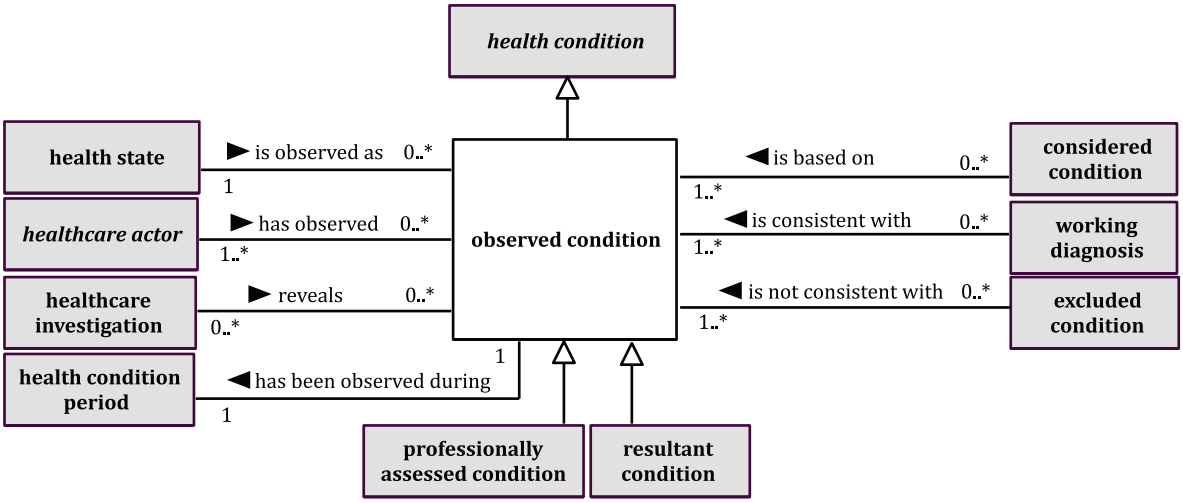

Figure 22 — Observed condition (UML representation)

6.4.1.1 Professionally assessed condition

Term: *professionally assessed condition*

Synonym: professionally assessed health condition

Definition: *observed condition* assessed by a *healthcare professional* concerning the genesis, the course, the severity or the impact of the *health state*

Table 18 lists the associations of this concept; a UML representation of the concept is shown in Figure 23.

Table 18 — Associations of *professionally assessed condition*

Specialization of	**Generalization of**
observed condition	working diagnosis

Association from		**Association name**	**Association to**	
0..*	prognostic condition	is based on	1..*	professionally assessed condition
0..*	professionally assessed condition	is identified by	1	healthcare professional

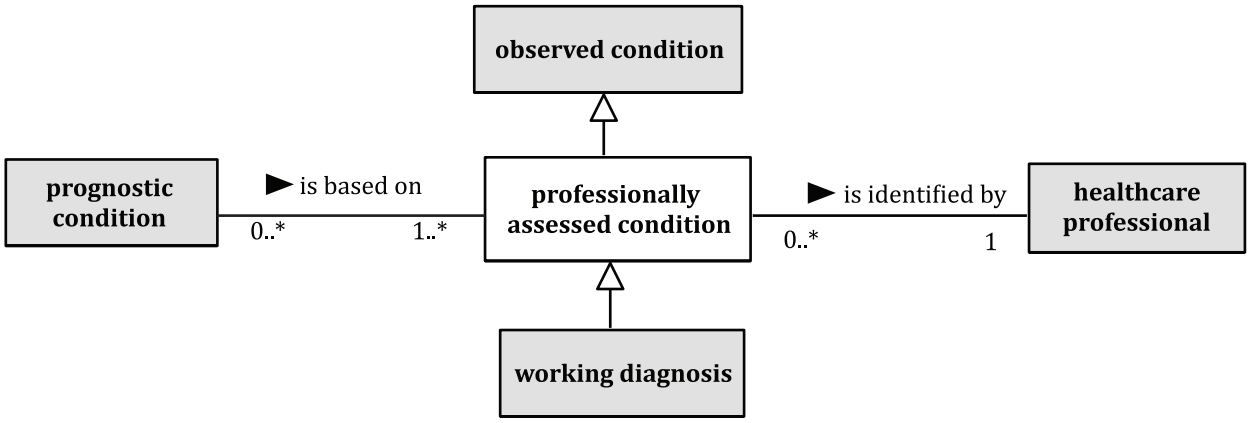

Figure 23 — Professionally assessed condition (UML representation)

6.4.1.2 Resultant condition

Term: *resultant condition*

Definition: *observed condition* representing an *output health state*

NOTE A resultant condition can represent the output health state after a single healthcare activity element, a bundle of healthcare investigations and/or healthcare treatments in a healthcare process and also the outcome after a complete clinical process.

EXAMPLES Healthcare process result, healthcare activity result.

Table 19 lists the associations of this concept; a UML representation of the concept is shown in Figure 24.

Table 19 — Associations of *resultant condition*

Specialization of		**Generalization of**		
observed condition				
Association from		**Association name**	**Association to**	
1	output health state	is observed as	0..*	resultant condition
0..*	resultant condition	Is input to	0..*	clinical process outcome evaluation

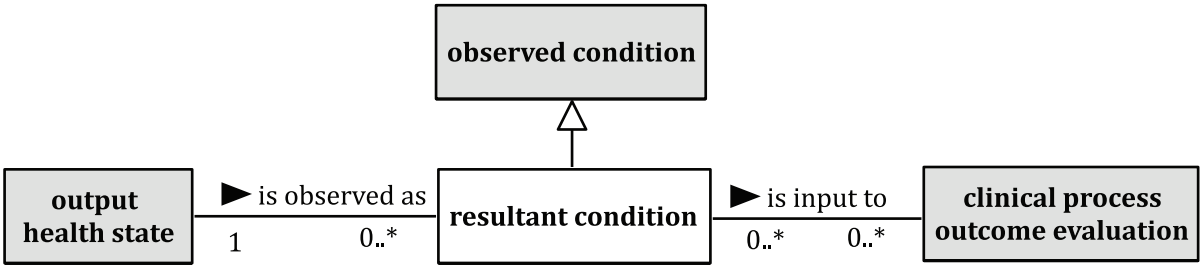

Figure 24 — Resultant condition (UML representation)

6.4.2 Potential health condition

Term: *potential health condition*

Definition: possible future or current *health condition* described by a *healthcare actor*

NOTE 1 A *potential health condition* is not yet observed, but represents an imagined, possible observation of aspects of a current or future health state.

NOTE 2 A *potential health condition* can only be fully supported through the use of one of its specializations.

Table 20 lists the associations of this concept; a UML representation of the concept is shown in Figure 25.

Table 20 — Associations of *potential health condition*

Specialization of	**Generalization of**
health condition	prognostic condition
	target condition
	risk condition
	considered condition

Association from		**Association name**	**Association to**	
1..*	healthcare actor	describes	0..*	potential health condition
0..*	potential health condition	represents potential aspects of	1	health state

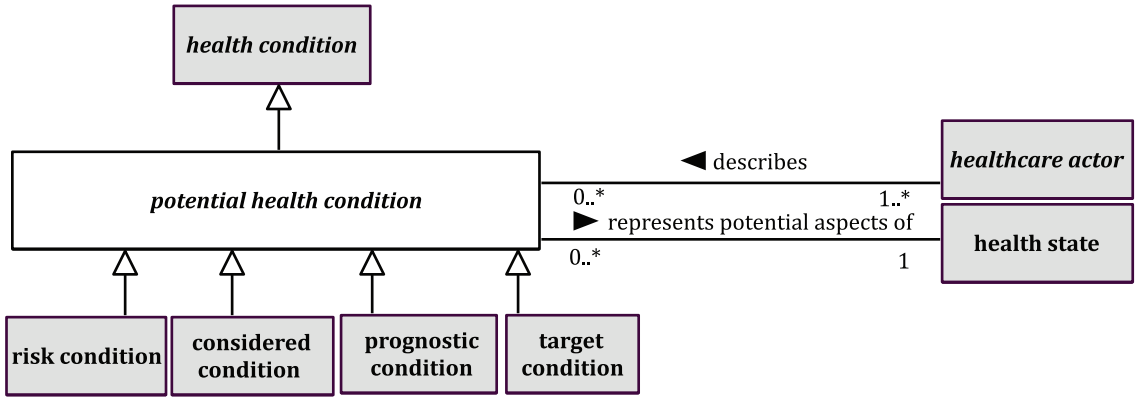

Figure 25 — Potential health condition (UML representation)

6.4.2.1 Considered condition

Term: *considered condition*

Synonym: considered health condition

Definition: *potential health condition* considered by a *healthcare actor* on the basis of one or more *observed conditions*

NOTE 1 A request for care normally includes a *health condition* or symptom observed by the *subject of care* and also a question about what the reason for that symptom might be. It is the *potential health condition* in this question (the *health condition* behind the symptom) that is called a *considered condition*.

NOTE 2 A *referral* within a *clinical process* is normally motivated by one or several *observed conditions* and/or *professionally assessed conditions*. However the *referral* also normally includes a question that the *healthcare investigation* is supposed to get an answer to. The question formulated as a *potential condition* is a *considered condition*.

NOTE 3 A *considered condition* remains considered until the associated *observed conditions* are changed or completed. *Healthcare investigation* and/or *healthcare treatment* result in new observations that can verify or not verify the (suspected) *considered condition*. When a *considered condition* is verified it is transformed into an *observed condition* and/or *professionally assessed condition* that also could be labelled as a *working diagnosis*. If a *considered condition* cannot be verified by relevant *healthcare activities* it is transformed into an *excluded condition*.

NOTE 4 A *working diagnosis* is often identified in the clinical process as a summary after the planned healthcare investigation are completed. A *working diagnosis* in this stage is often called a diagnosis. An excluded condition could correspondingly be called a negation of a *working diagnosis*.

EXAMPLES Diagnostic hypothesis, any candidate in a differential diagnosis set.

Table 21 lists the associations of this concept; a UML representation of the concept is shown in Figure 26.

Table 21 — Associations of *considered health condition*

Specialization of	**Generalization of**
potential health condition	working diagnosis
	excluded condition

Association from		**Association name**	**Association to**	
0..*	considered condition	is based on	1..*	observed condition

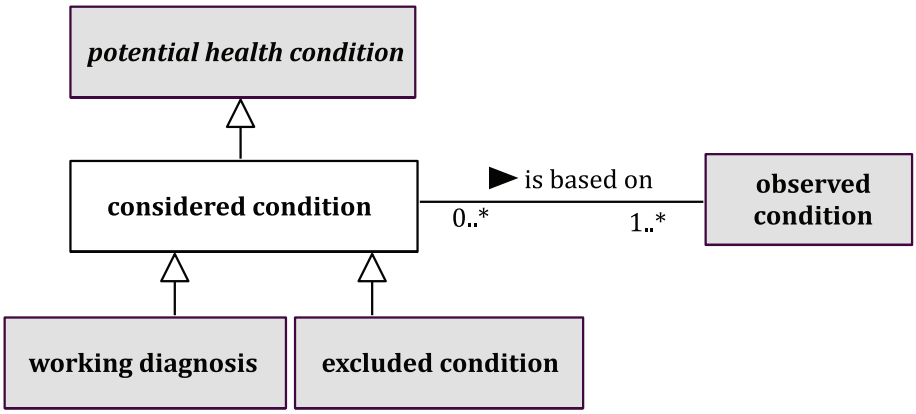

Figure 26 — Considered condition (UML representation)

6.4.2.1.1 Working diagnosis

Term: *working diagnosis*

Synonym: working hypothesis

Definition: *considered condition* that one or more *healthcare professionals* have determined to be the most consistent with the currently known *observed conditions*

NOTE 1 A *working diagnosis* is used as a label for the *considered condition* that one or more *healthcare professionals* assess as the most probable *health condition* and that could be concluded after further observations. The basis for such assessments is the already *observed conditions*.

NOTE 2 Different *healthcare professionals* may make different interpretations and assessments of the *observed conditions* and thereby come to different conclusions and different *working diagnosis*.

Table 22 lists the associations of this concept; a UML representation of the concept is shown in Figure 27.

Table 22 — Associations of *working diagnosis*

Specialization of	**Generalization of**
professionally assessed condition	
considered condition	

Association from		**Association name**	**Association to**	
1..*	healthcare professional	has determined	0..*	working diagnosis
0..*	working diagnosis	is consistent with	1..*	observed condition

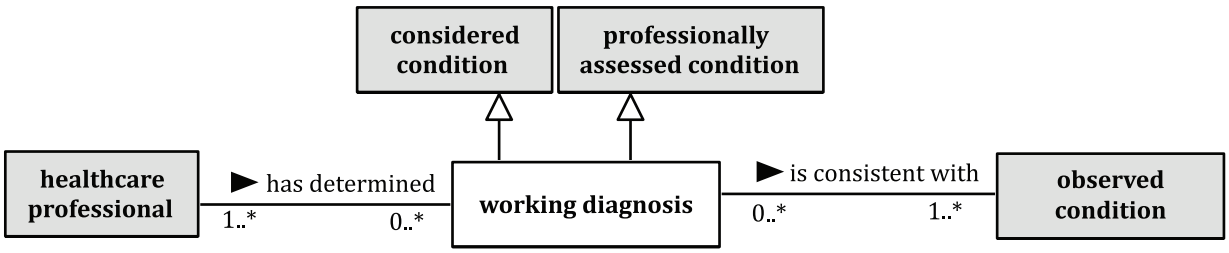

Figure 27 — Working diagnosis (UML representation)

6.4.2.1.2 Excluded condition

Term: *excluded condition*

Synonyms: discounted condition, non-verified condition, ruled out condition, ruled out considered condition

Definition: *considered condition* that one or more *healthcare professionals* have determined not to be consistent with the known *observed conditions*

Table 23 lists the associations of this concept; a UML representation of the concept is shown in Figure 28.

Table 23 — Associations of *excluded condition*

Specialization of	**Generalization of**
considered condition	

Association from		**Association name**	**Association to**	
1..*	healthcare professional	has ruled out	0..*	excluded condition
0..*	excluded condition	is not consistent with	1..*	observed condition

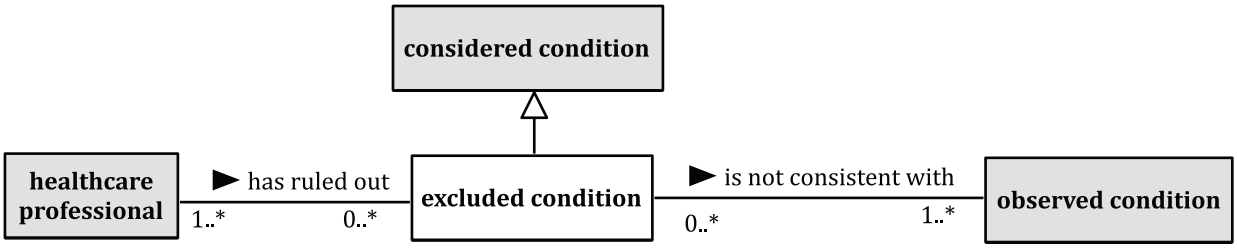

Figure 28 — Excluded condition (UML representation)

6.4.2.2 Target condition

Term: *target condition*

Synonyms: target health condition, intended outcome

Definition: *potential health condition* representing *health objectives* and/or *healthcare goals*

NOTE Assessment of needs for *healthcare activities* includes identification of *health objectives* and/or *healthcare goals*. These inform decisions about relevant activities to create or update the *care plan*.

EXAMPLE 1 The *target condition* for a worker that arrived at the Emergency Room with a broken arm is to be fully functional for work in the shortest time period.

EXAMPLE 2 The *target condition* of a newly diagnosed diabetic adolescent boy is maintenance of his HbA1c at less than 48 mmol/mol. (HbA1c is a lab test that shows the average level of blood sugar (glucose) over the previous 3 months; it shows how well diabetes is being controlled).

Table 24 lists the associations of this concept; a UML representation of the concept is shown in Figure 29.

Table 24 — Associations of *target condition*

Specialization of		**Generalization of**		
potential health condition				
Association from		**Association name**	**Association to**	
0..*	target condition	represents	0..*	health objective
1..*	target condition	is input to	0..*	clinical process outcome evaluation
0..*	target condition	represents	0..*	healthcare goal

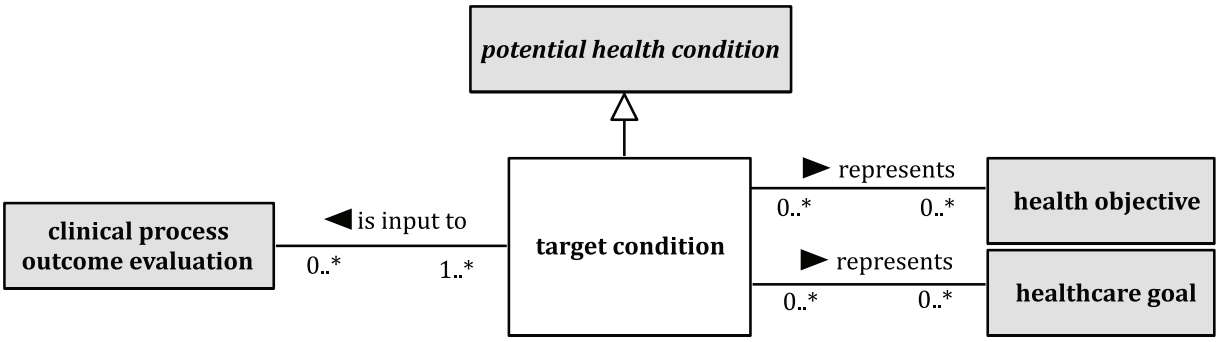

Figure 29 — Target condition (UML representation)

6.4.2.3 Prognostic condition

Term: *prognostic condition*

Synonym: prognostic health condition

Definition: *potential health condition* representing the expected course of a *health state* as assessed by *healthcare professionals*

Table 25 lists the associations of this concept; a UML representation of the concept is shown in Figure 30.

Table 25 — Associations of *prognostic condition*

Specialization of		**Generalization of**	
potential health condition			
Association from		**Association name**	**Association to**
0..*	prognostic condition	is based on	1..* professionally assessed condition
1..*	healthcare professional	identifies	0..* prognostic condition

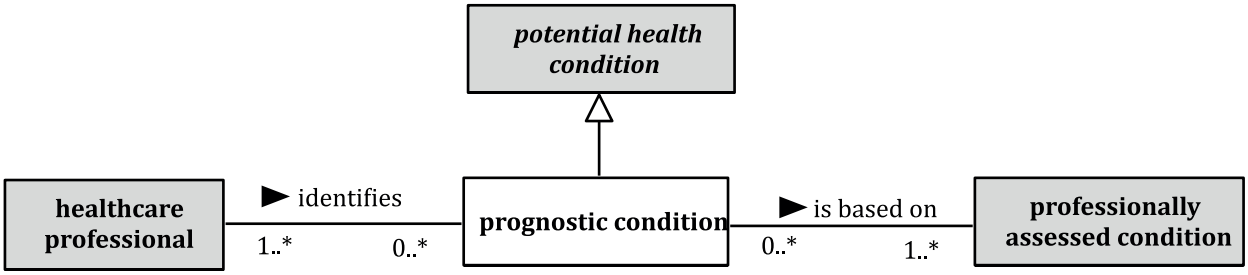

Figure 30 — Prognostic condition (UML representation)

6.4.2.4 Risk condition

Term: *risk condition*

Synonym: risk health condition

Definition: *potential health condition* representing an unintended future *health state*

NOTE While a risk is defined as the combination of a probability of an event and its consequences, the *risk condition* deals only with the consequences.

Table 26 lists the associations of this concept; a UML representation of the concept is shown in Figure 31.

Table 26 — Associations of *risk condition*

Specialization of	**Generalization of**
potential health condition	

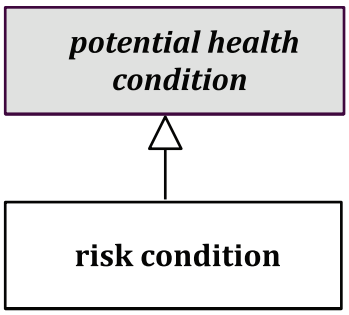

Figure 31 — Risk condition (UML representation)

6.4.2.5 Health problem

Term: *health problem*

Definition: *health condition* considered by a *health care actor* to be a problem

NOTE *Health problems* can be single observations but are usually more compound as a summary of several observations. Single observations are often criteria for the more compound *health condition* considered to be a *health problem*.

EXAMPLES Diabetes, stroke, heredity for breast cancer.

Table 27 lists the associations of this concept; a UML representation of the concept is shown in Figure 32.

Table 27 — Associations of *health problem*

Specialization of	**Generalization of**
health condition	

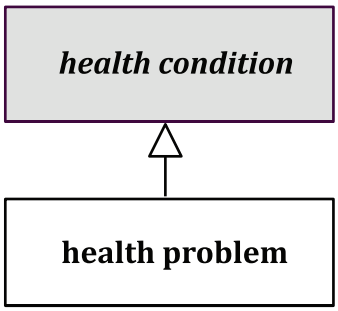

Figure 32 — Health problem (UML representation)

6.5 Health state

Term: *health state*

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

NOTE 1 An observation of a *health state* is a *health condition*. A *health state* may possibly give way to more than one observation, resulting in more than one *health condition*. The underlying *health state* is nevertheless present even if not perceived by an observer, for example, the *subject of care* having a cancer before it gives symptoms.

NOTE 2 In ICF (the International Classification of Functioning, Disability and Health) of the WHO, the concept of health is described. ICF identifies five health components; body function, body structure, activity, participation and environmental factors.

Table 28 lists the associations of this concept; a UML representation of the concept is shown in Figure 33.

Table 28 — Associations of *health state*

Specialization of		**Generalization of**		
		input health state		
		output health state		
Association from		**Association name**	**Association to**	
1	subject of care	has	1	health state

Table 28 *(continued)*

1	health state	is observed as	0..*	observed condition
0..*	potential health condition	represents potential aspects of	1	health state
0..*	healthcare treatment	influences	1	health state
0..*	health need	is deficit in	1	health state
0..*	healthcare investigation	clarifies	1	health state

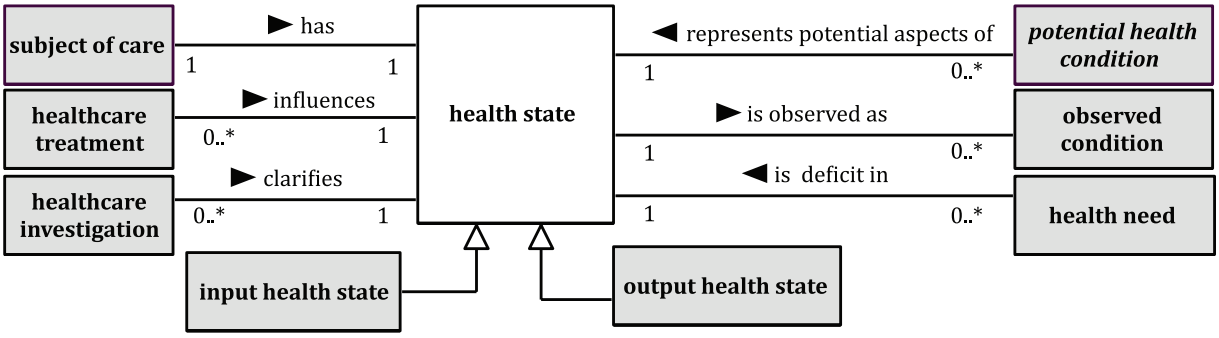

Figure 33 — Health state (UML representation)

6.5.1 Input health state

Term: *input health state*

Definition: *health state* at the initiation of *healthcare process*

NOTE The *output health state* from one *healthcare process* may be the *input health state* to a subsequent *healthcare process*.

Table 29 lists the associations of this concept; a UML representation of the concept is shown in Figure 34.

Table 29 — Associations of *input health state*

Specialization of	**Generalization of**
health state	

Association from		**Association name**	**Association to**	
0..1	health condition evolution	relates to	1	input health state
0..1	input health state	is input to	1	healthcare process

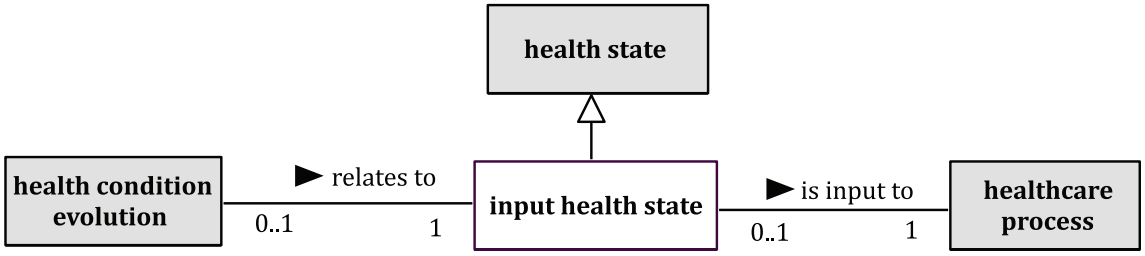

Figure 34 — Input health state (UML representation)

6.5.2 Output health state

Term: *output health state*

Synonym: outcome

Definition: *health state* when a *healthcare process* ends

Table 30 lists the associations of this concept; a UML representation of the concept is shown in Figure 35.

Table 30 — Associations of *output health state*

Specialization of	**Generalization of**
health state	

Association from		**Association name**	**Association to**	
1	healthcare process	has output	0..1	output health state
1	output health state	is observed as	0..*	resultant condition

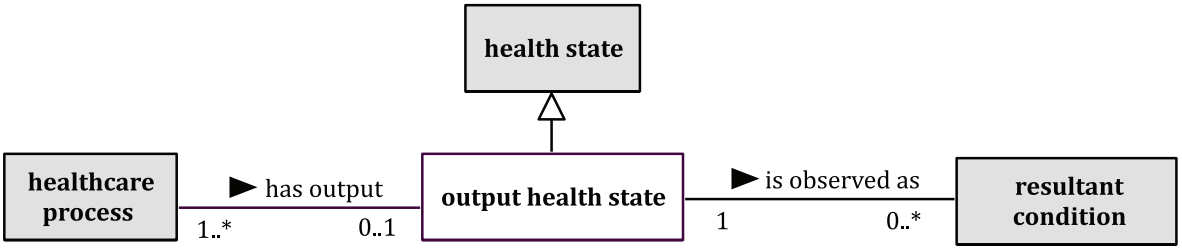

Figure 35 — Output health state (UML representation)

6.5.3 Health need

Term: *health need*

Definition: deficit in the current *health state* compared to aspects of a desired future *health state*

NOTE 1 A *health need* is the deficit in a *subject of care's* health state.

NOTE 2 The current *health state* is observed as *observed conditions*.

NOTE 3 The desired future *health state* can be a *health objective* expressed as *target conditions*.

NOTE 4 The *health need* can be identified and formulated by the *subject of care* or by any other *healthcare actor*.

NOTE 5 *Health needs* are the motivations/indications for *healthcare activities* and are the basic input to *healthcare needs assessments*.

Table 31 lists the associations of this concept; a UML representation of the concept is shown in Figure 36.

Table 31 — Associations of *health need*

Association from		**Association name**	**Association to**	
1	subject of care	has or has had	0..*	health need
0..*	health need	is background for	0..*	reason for demand for care
1	health need	is considered during	0..*	healthcare needs assessment
0..*	health need	is deficit in	1	health state

Table 31 *(continued)*

1..*	needed healthcare activity	addresses	1..*	health need
0..*	health objective	addresses	1..*	health need

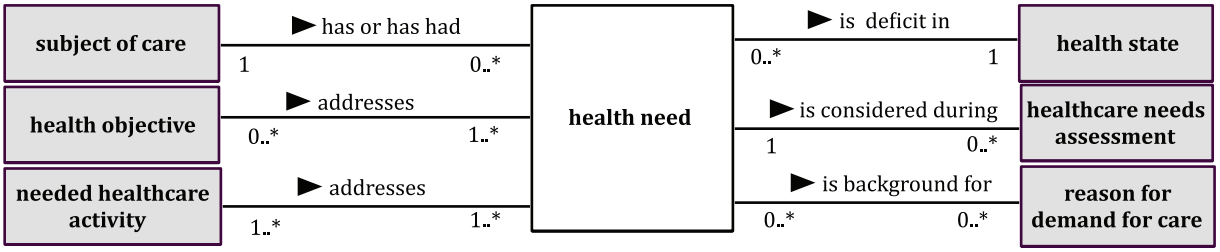

Figure 36 — Health need (UML representation)

6.6 Health thread

Term: *health thread*

Definition: defined association between *healthcare matters as* determined by one or more *healthcare actors*

NOTE 1 A *health thread* reconciles a range of *healthcare matters* reflecting the variety of scopes of *healthcare actors*, particularly of *healthcare providers*.

NOTE 2 A *health thread* inherently associates the *healthcare processes* as well as the *healthcare activity period elements* referring to those *healthcare matters*.

NOTE 3 A *health thread* may be established by a team (e.g. a coordination committee).

NOTE 4 A *health thread* can be built step-by-step, by allowing each *healthcare professional* to add their perspective into a common *health thread*.

NOTE 7 Under the responsibility of a designated *healthcare actor*, a *health thread* linking several *healthcare matters* can describe an *episodes of care bundle*, for instance, a partial or comprehensive synthesis of *healthcare actor* related *episodes of care*.

NOTE 8 A collective decision (before, during or after the healthcare interventions) may define a *health thread* and so the idea of the 'episode' accepted by all the *healthcare professionals* involved.

NOTE 9 Two *health conditions* may sometimes only be recognized as belonging to the same *health thread* late in the process of care. Conversely, two *health conditions* thought initially to belong to the same *health thread* may need to be separated later.

NOTE 10 Since a *health thread* links any number of *healthcare matters*; it also may link *health threads* linking other *health issues*. Hence, a *health thread* may be considered an aggregation of *health issues* and/or *health threads*.

EXAMPLES

A low back pain, known for many years by the *subject of care's* GP, treated several times by the physiotherapist who labelled it a scoliosis and currently a candidate for a specific orthopaedic intervention.

A case labelled social problem by the GP after being treated by the psychiatrist for minor depression and the rheumatologist for osteoarthritis.

Type 2 diabetes treated by a GP, a nurse, an endocrinologist and a vascular surgeon.

The *health conditions* included in a *healthcare process*.

Table 32 lists the associations of this concept; a UML representation of the concept is shown in Figure 37.

Table 32 — Associations of *health thread*

Specialization of	**Generalization of**
	clinical process interest
	health condition evolution
	health problem list

Association from		**Association name**	**Association to**	
1	health thread	delineates	0..1	episodes of care bundle
1	health thread	delineates	0..1	health concern
0..*	health thread	links	0..*	healthcare matter
0..*	health thread	links	0..*	health thread
1..*	healthcare actor	defines	0..*	health thread
0..*	continuity facilitator mandate	has topic	0..*	health thread
0..*	care plan	addresses	0..*	health thread

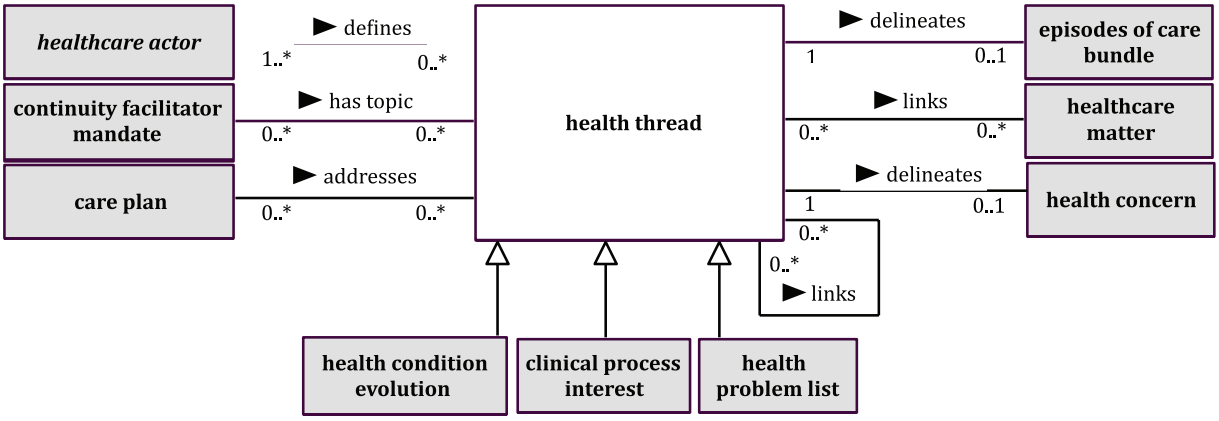

Figure 37 — Health thread (UML representation)

6.6.1 Clinical process interest

Term: *clinical process interest*

Definition: *health thread* comprising all *healthcare matters* related to a specific *clinical process*

NOTE A *clinical process interest* makes it possible

- to make all information related to the *healthcare matters* in a *clinical process* available to all *healthcare actors* that have the needs for that and thereby supporting continuity of care
- for documentation concerning a *clinical process* to follow the *subject of care* across borders of *healthcare providers* and organizational units and as such avoid unnecessary duplication of documentation (to create a *health concern*)
- to track all information in a *clinical process* to create a *health concern* for that *clinical process* and for secondary use of information in follow up
- to follow the value added by *healthcare activities* through documented changes in *health conditions* during all stages of the *clinical process*

- to create a *health concern* in order to constrain the availability of information related to a certain *clinical process* due to the integrity needs for the subject of care

Table 33 lists the associations of this concept; a UML representation of the concept is shown in Figure 38.

Table 33 — Associations of *clinical process interest*

Specialization of	**Generalization of**
health thread	

Association from		**Association name**	**Association to**	
1	clinical process	has	0..1	clinical process interest

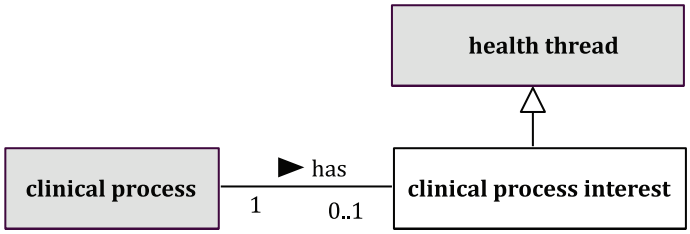

Figure 38 — Clinical process interest (UML representation)

6.6.2 Health problem list

Term: *health problem list*

Synonym: healthcare problem list

Definition: *health thread* linking a set of *health problems*

Table 34 lists the associations of this concept; a UML representation of the concept is shown in Figure 39.

Table 34 — Associations of *health problem list*

Specialization of	**Generalization of**
health thread	

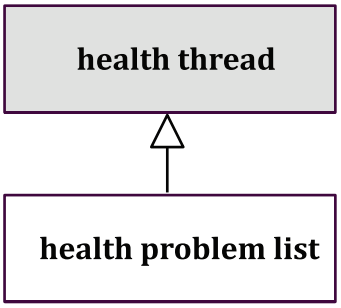

Figure 39 — Health problem list (UML representation)

6.6.3 Health condition evolution

Term: *health condition evolution*

Definition: *health thread* showing the evolution of *health conditions* during a *healthcare process*, starting with the *health condition* that represents the *input health state*

Table 35 lists the associations of this concept; a UML representation of the concept is shown in Figure 40.

Table 35 — Associations of *health condition evolution*

Specialization of		**Generalization of**		
health thread				
Association from		**Association name**	**Association to**	
0..1	health condition evolution	relates to	1	input health state
0..*	health condition evolution	shows the evolution of	1..*	health condition

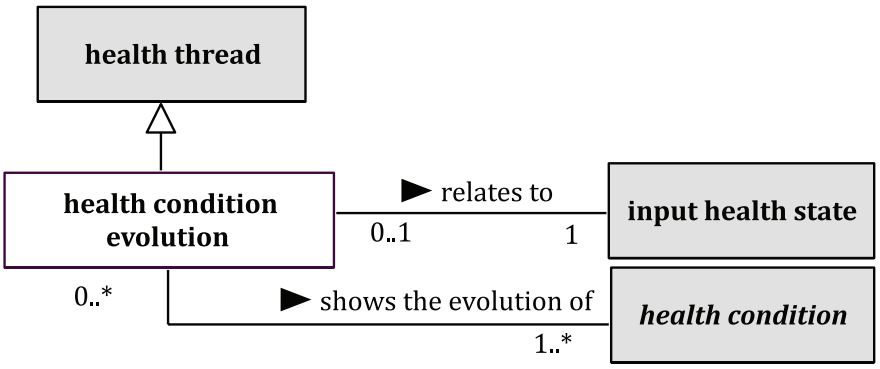

Figure 40 — Health condition evolution (UML representation)

7 Concepts related to activities

7.1 General

A model showing the associations between the concepts related to activity and the other concepts defined in this International Standard is shown in Figures 41 and 42. For further detail about the diagram notation, please refer to 0.7 in the Introduction.

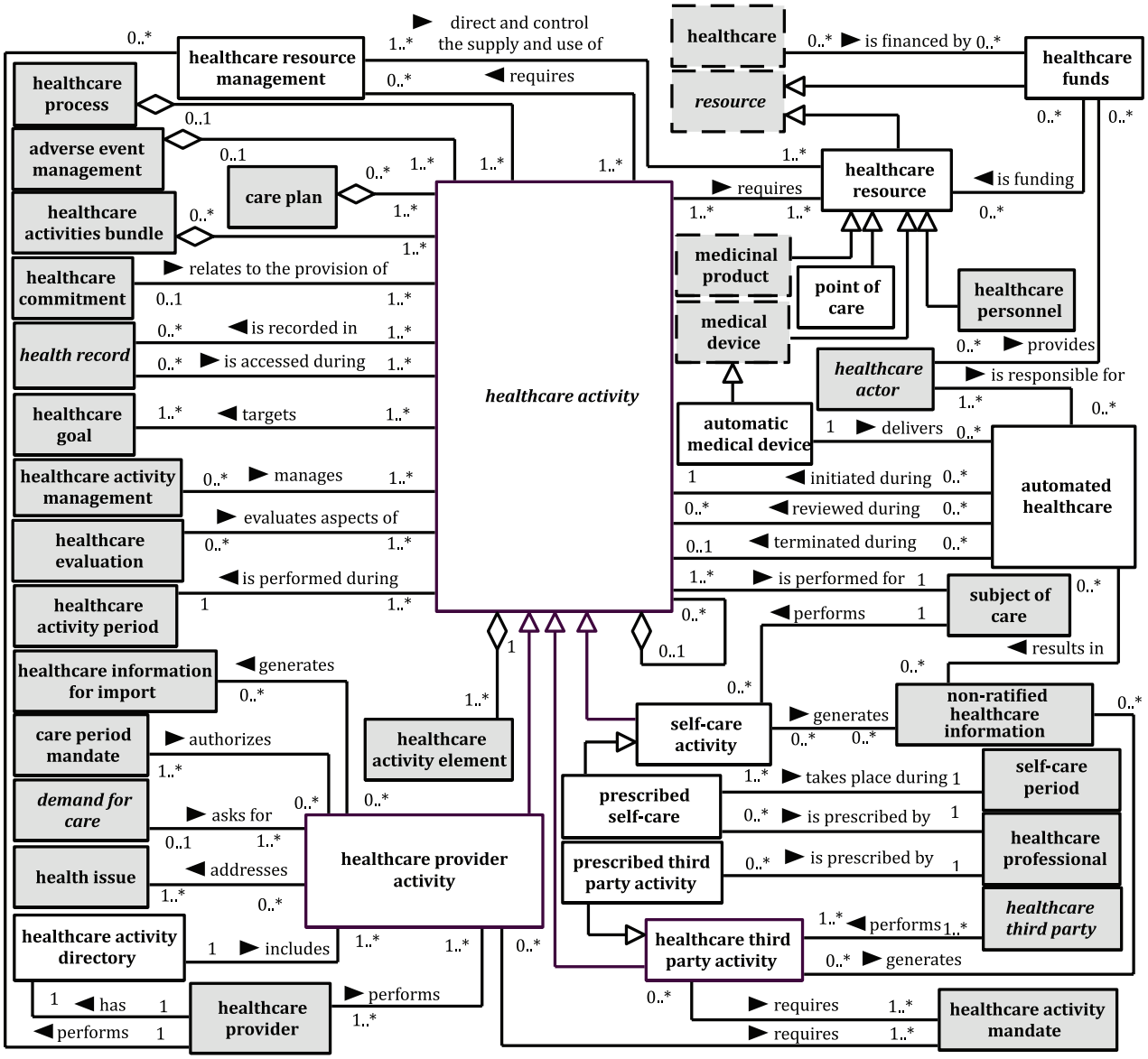

Figure 41 — Comprehensive UML diagram of concepts related to activities (i)

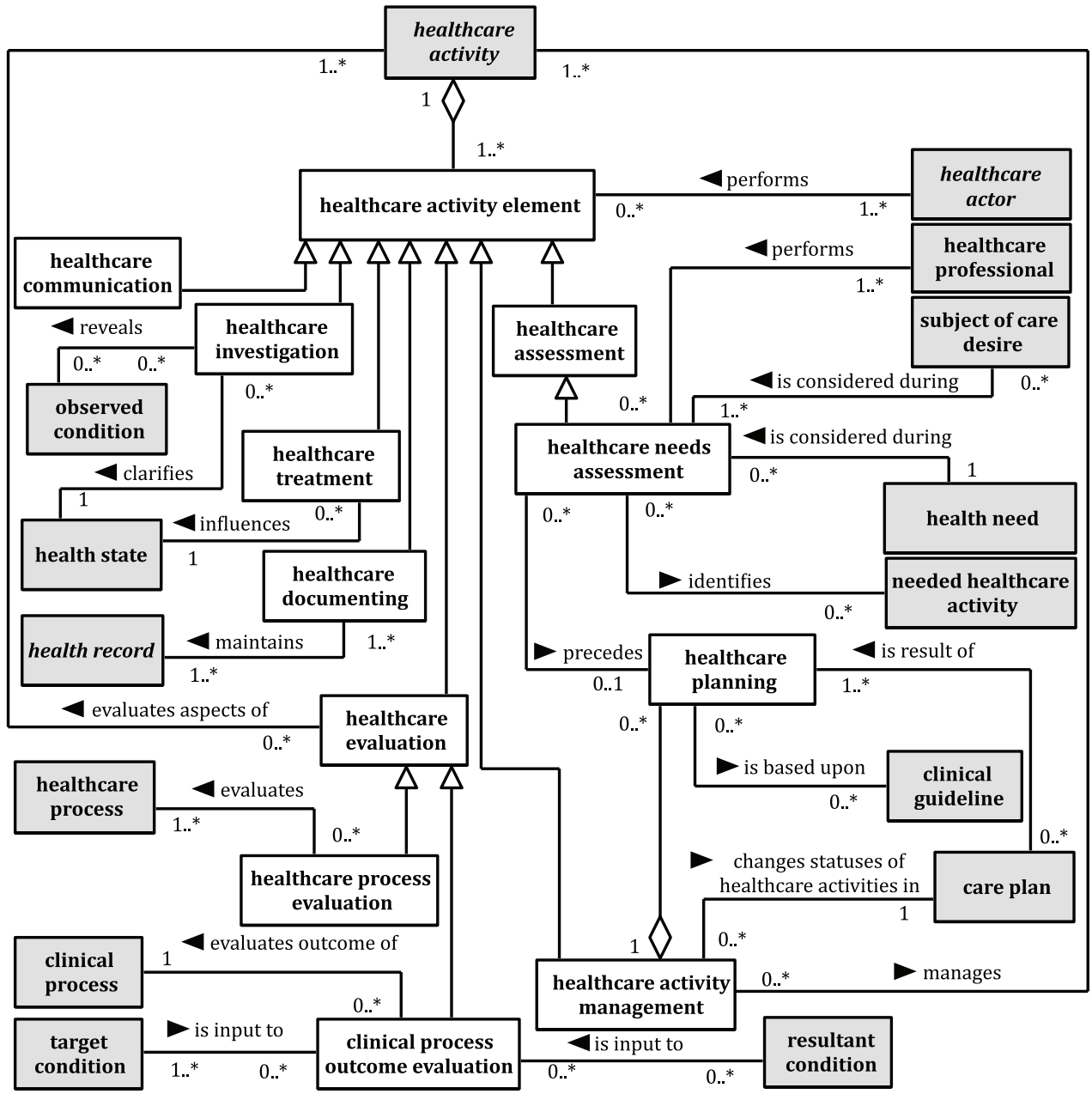

Figure 42 — Comprehensive UML diagram of concepts related to activities (ii)

7.2 Healthcare activity

Term: *healthcare activity*

Definition: activity intended directly or indirectly to improve or maintain a *health state*

NOTE 1 Each specialization of this concept represents *healthcare activities* performed by a specialization of healthcare actor.

NOTE 2 Different types of *healthcare activity elements* (e.g. *healthcare investigation* or *healthcare treatment)* may be performed during a healthcare activity.

NOTE 3 See the concepts *healthcare provider activity, self-care activity, healthcare third party activity* and *automated healthcare* when it comes to the recording of information that are the result of *healthcare activities* (e.g. ratified observations).

EXAMPLE A blood pressure measurement completed by a qualified nurse including the *healthcare activity elements* of taking, documenting and evaluation.

Table 36 lists the associations of this concept; a UML representation of the concept is shown in Figure 43.

Table 36 — Associations of *healthcare activity*

Specialization of		**Generalization of**	
		healthcare provider activity	
		healthcare third party activity	
		self-care activity	
Component of		**Aggregation of**	
0..*	care plan	0..*	healthcare activity
0..1	healthcare process	1..*	healthcare activity element
0..*	healthcare activities bundle		
0..1	healthcare activity		
0..1	adverse event management		

Association from		**Association name**	**Association to**	
1..*	healthcare activity	is performed for	1	subject of care
1..*	healthcare activity	targets	1..*	healthcare goal
1..*	healthcare activity	is recorded in	0..*	health record
0..*	health record	is accessed during	1..*	healthcare activity
1..*	healthcare activity	is performed during	1	healthcare activity period
1..*	healthcare activity	requires	1..*	healthcare resource
1..*	healthcare activity	requires	0..*	healthcare resource management
0..1	healthcare commitment	relates to the provision of	1..*	healthcare activity
0..*	healthcare activity management	manages	1..*	healthcare activity
0..*	automated healthcare	initiated during	1	healthcare activity
0..*	automated healthcare	reviewed during	0..*	healthcare activity
0..*	automated healthcare	terminated during	0..1	healthcare activity
0..*	healthcare evaluation	evaluates aspects of	1..*	healthcare activity

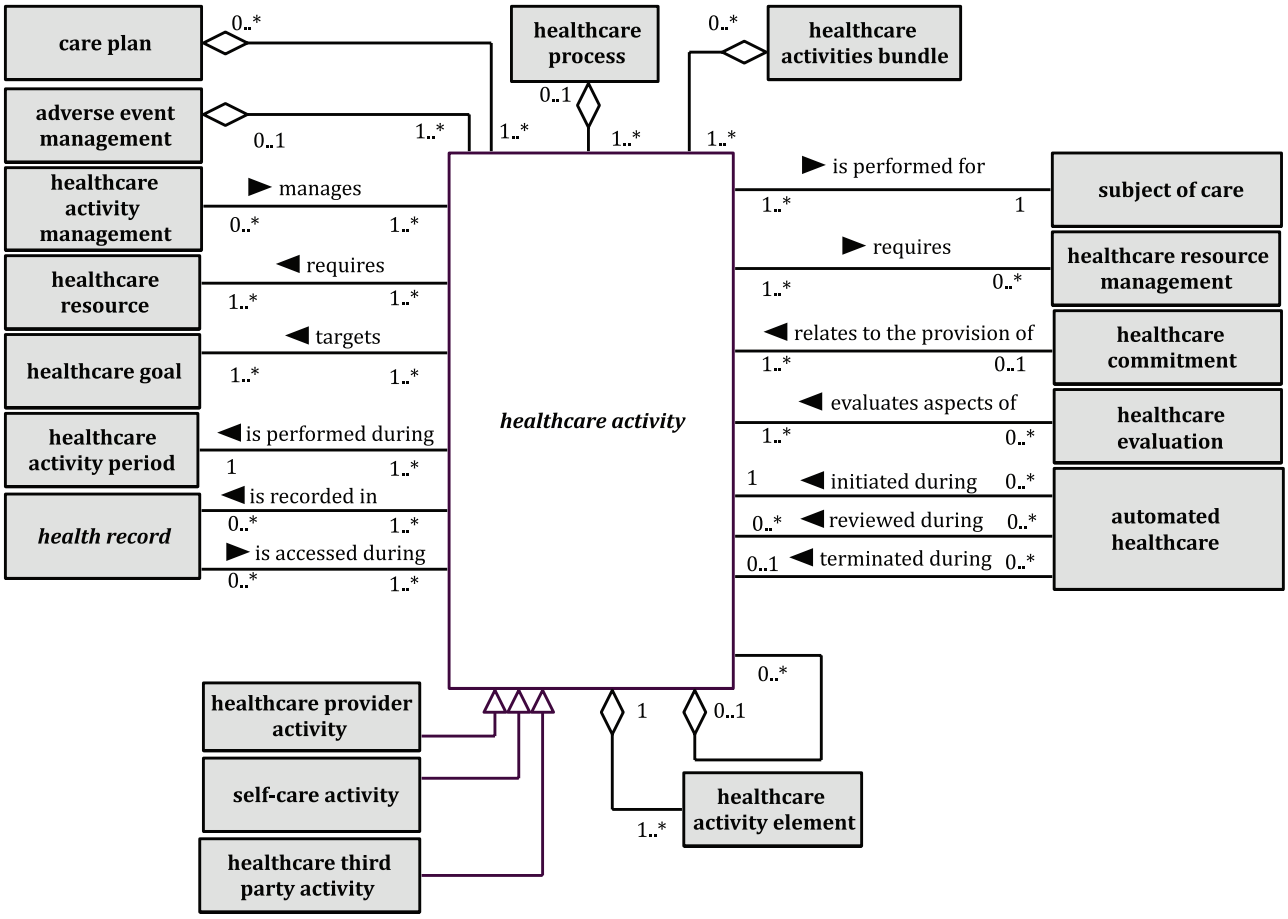

Figure 43 — Healthcare activity (UML representation)

7.2.1 Healthcare provider activity

Term: *healthcare provider activity*

Definition: *healthcare activity* performed by a *healthcare provider*

NOTE 1 A *healthcare provider activity* can be performed in relation to several *healthcare activity period elements* of the same *healthcare activity period*.

NOTE 2 When the *healthcare provider* is a *healthcare organization*, the *healthcare activities* are performed by the *healthcare personnel* of that *healthcare organization*.

Table 37 lists the associations of this concept; a UML representation of the concept is shown in Figure 44.

Table 37 — Associations of *healthcare provider activity*

Specialization of	**Generalization of**
healthcare activity	

Association from		**Association name**	**Association to**	
0..*	healthcare provider activity	addresses	1..*	health issue
0..*	healthcare provider activity	generates	0..*	healthcare information for import
1..*	healthcare provider	performs	1..*	healthcare provider activity
1..*	care period mandate	authorizes	0..*	healthcare provider activity

Table 37 *(continued)*

0..1	demand for care	asks for	1..*	healthcare provider activity
0..*	healthcare provider activity	requires	1..*	healthcare activity mandate
1	healthcare activity directory	includes	1..*	healthcare provider activity

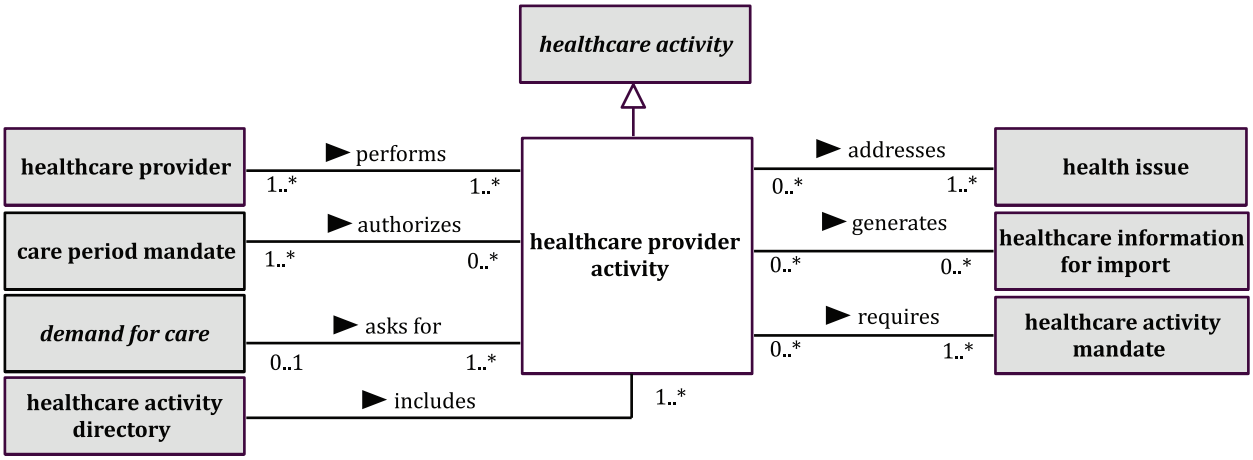

Figure 44 — Healthcare provider activity (UML representation)

7.2.2 Healthcare activity directory

Term: *healthcare activity directory*

Definition: directory of the *healthcare activities* offered by a *healthcare provider*

NOTE 1 The *healthcare activity directory* includes those *healthcare activities* that the *healthcare provider's healthcare personnel* can perform, not those that are actually available at the time of *healthcare* delivery. The ability to perform a *healthcare activity* implies that the *healthcare provider* has the necessary resources.

NOTE 2 The *healthcare activity directory* is related to the management of *healthcare processes.*

NOTE 3 *Healthcare providers* may also have a *healthcare service directory* This directory includes the services that can be delivered by *healthcare processes* using the *healthcare activities* included in the *healthcare activity directory.*

Table 38 lists the associations of this concept; a UML representation of the concept is shown in Figure 45.

Table 38 — Associations of *healthcare activity directory*

Association from		Association name	Association to	
1	healthcare activity directory	includes	1..*	healthcare provider activity
1	healthcare provider	has	1	healthcare activity directory

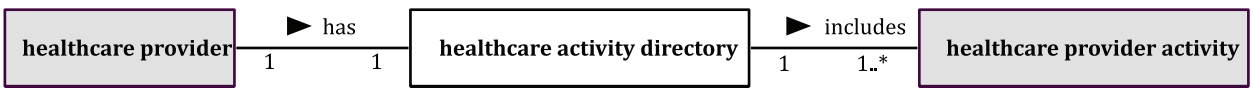

Figure 45 — Healthcare activity directory (UML representation)

7.2.3 Self-care activity

Term: *self-care activity*

Deprecated term: health self-care activity

Definition: *healthcare activity* performed by the *subject of care*

NOTE 1 There are two kinds of *self-care activities* that should be distinguished: a) *Prescribed self-care* that is included in a *care plan* and the documentation is included in a *professional health record;* b) Self performed health related activities that are not prescribed.

NOTE 2 In EN 13940–1:2007 health self-care activity was the preferred term for this concept.

EXAMPLES Self injection of insulin, self-measurement of blood pressure, or of glycaemia.

Table 39 lists the associations of this concept; a UML representation of the concept is shown in Figure 46.

Table 39 — Associations of *self-care activity*

Specialization of		**Generalization of**		
healthcare activity		prescribed self-care		
Association from		**Association name**	**Association to**	
0..*	self-care activity	generates	0..*	non-ratified healthcare information
1	subject of care	performs	0..*	self-care activity

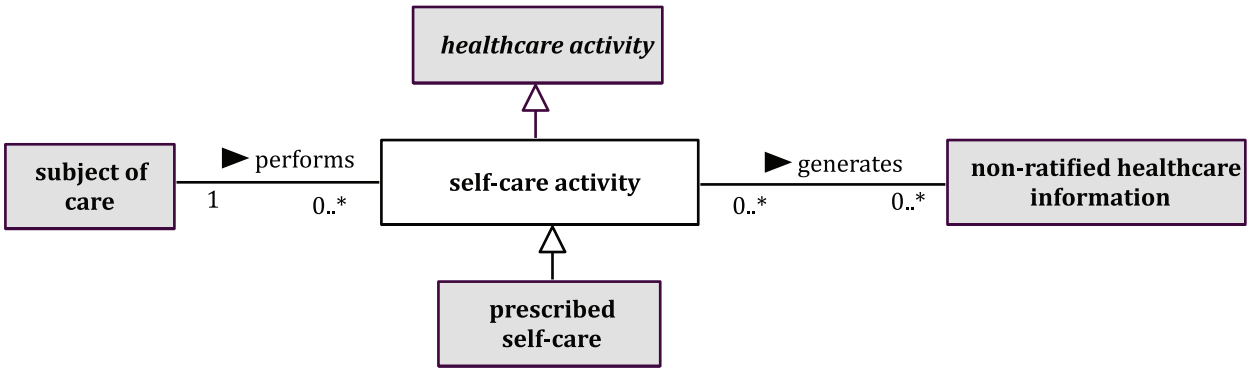

Figure 46 — Self-care activity (UML representation)

7.2.4 Prescribed self-care

Term: *prescribed self-care*

Definition: *self-care activity* prescribed by a *healthcare professional*

Table 40 lists the associations of this concept; a UML representation of the concept is shown in Figure 47.

Table 40 — Associations of *prescribed self-care*

Specialization of		**Generalization of**		
self-care activity				
Association from		**Association name**	**Association to**	
0..*	prescribed self-care	is prescribed by	1	healthcare professional
1..*	prescribed self-care	takes place during	1	self-care period

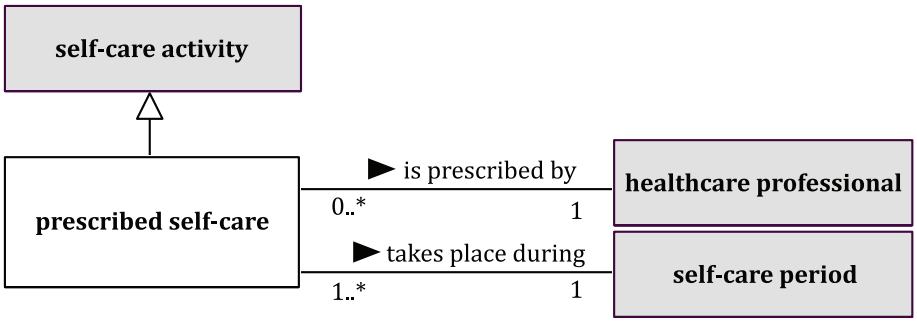

Figure 47 — Prescribed self-care (UML representation)

7.2.5 Healthcare third party activity

Term: *healthcare third party activity*

Synonym: healthcare contributing activity

Definition: *healthcare activity* performed by a *healthcare third party*

NOTE 1 There are two kinds of *healthcare third party activities* that should be distinguished.

Prescribed contributing care that is included in a *care plan* and the documentation is included in a *health record*.

Healthcare third party activities that are not prescribed.

NOTE 2 In EN 13940–1:2007 healthcare contributing activity was the preferred term for this concept.

EXAMPLES The *healthcare treatment* of a bedsore by a *subject of care's* relation, *healthcare treatment* on advice by a chemist.

Table 41 lists the associations of this concept; a UML representation of the concept is shown in Figure 48.

Table 41 — Associations of *healthcare third party activity*

Specialization of	**Generalization of**
healthcare activity	prescribed third party activity

Association from		**Association name**	**Association to**	
0..*	healthcare third party activity	generates	0..*	non-ratified healthcare information
0..*	healthcare third party activity	requires	1..*	healthcare activity mandate
1..*	healthcare third party	performs	1..*	healthcare third party activity

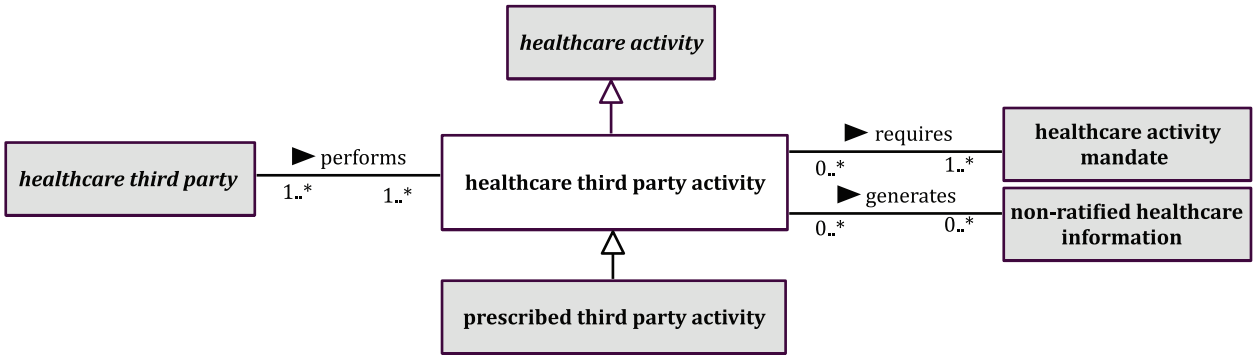

Figure 48 — Healthcare third party activity (UML representation)

7.2.6 Prescribed third party activity

Term: *prescribed third party activity*

Definition: *healthcare third party activity* prescribed by a *healthcare professional*

Table 42 lists the associations of this concept; a UML representation of the concept is shown in Figure 49.

Table 42 — Associations of *prescribed third party activity*

Specialization of		**Generalization of**		
healthcare third party activity				
Association from		**Association name**	**Association to**	
0..*	prescribed third party activity	is prescribed by	1	healthcare professional

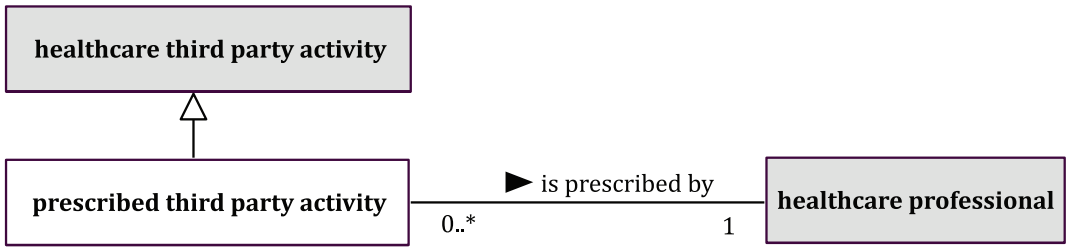

Figure 49 — Prescribed healthcare third party (UML representation)

7.2.7 Healthcare activity element

Term: *healthcare activity element*

Definition: element of *healthcare activity* that addresses one type of purpose

NOTE *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*.

Table 43 lists the associations of this concept; a UML representation of the concept is shown in Figure 50.

Table 43 — Associations of *healthcare activity element*

Specialization of			**Generalization of**		
			healthcare investigation		
			healthcare assessment		
			healthcare treatment		
			healthcare evaluation		
			healthcare documenting		
			healthcare communication		
			healthcare activity management		
Component of			**Aggregation of**		
1	healthcare activity				
Association from		**Association name**	**Association to**		
1..*	healthcare actor	performs	0..*	healthcare activity element	

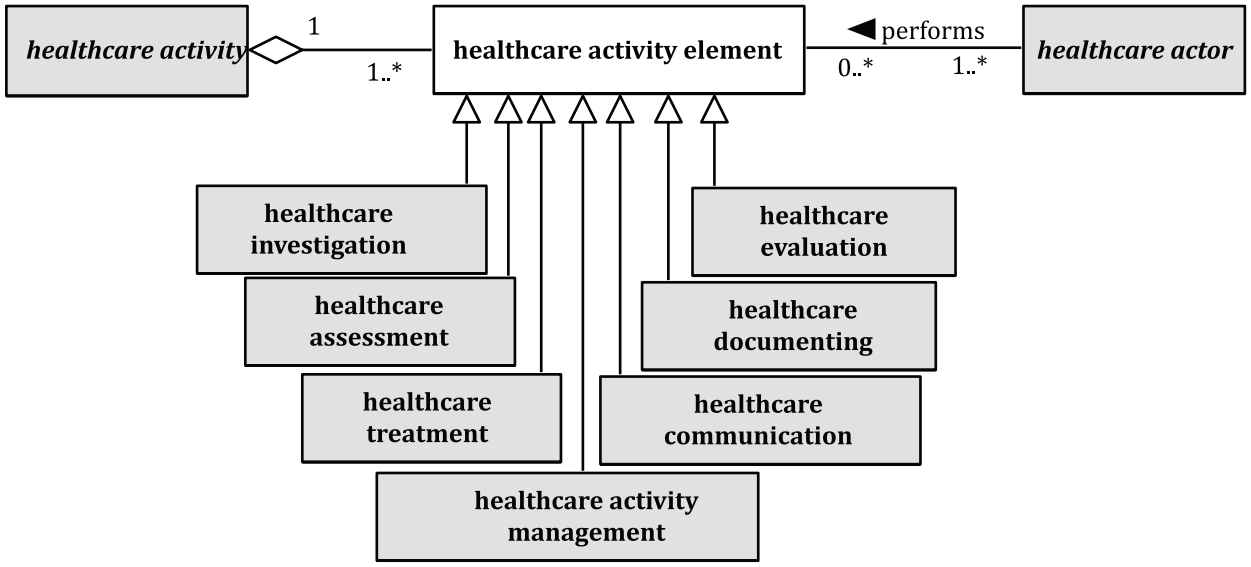

Figure 50 — Healthcare activity element (UML representation)

7.2.7.1 Healthcare treatment

Term: *healthcare treatment*

Definition: *healthcare activity element* intended to directly improve or maintain a *health state*

NOTE 1 The treatment of a *subject of care*'s *health state*, based on that *subject of care's health conditions*, is a part of the *clinical process* considered from a therapeutic perspective.

NOTE 2 *Healthcare treatment* is intended to contribute to fulfilling the assessed health need.

NOTE 3 Prevention is a type of *healthcare treatment* where the risk of a *health condition* is treated.

NOTE 4 *Healthcare treatment* includes all types of activities that intend to influence the health state including, for example, rehabilitation, palliative care, education of subjects of care, caring, etc.

Table 44 lists the associations of this concept; a UML representation of the concept is shown in Figure 51.

Table 44 — Associations of *healthcare treatment*

Specialization of		**Generalization of**		
healthcare activity element				
Association from		**Association name**	**Association to**	
0..*	healthcare treatment	influences	1	health state

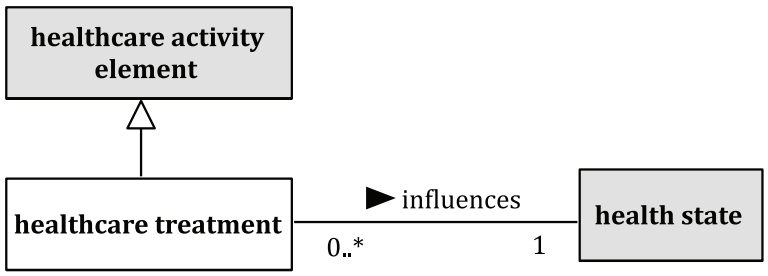

Figure 51 — Healthcare treatment (UML representation)

7.2.7.2 Healthcare investigation

Term: *healthcare investigation*

Definition: *healthcare activity element* with the intention to clarify one or more *health conditions* of a *subject of care*

NOTE 1 *Healthcare investigations* add and improve information about aspects of a *health state.*

NOTE 2 Some primary *healthcare investigations* can sometimes have an intended or secondary therapeutic effect, while some activities can be both investigating and therapeutic by essence (e.g. a fibroscopy, interventional cardiology, etc.)

Table 45 lists the associations of this concept; a UML representation of the concept is shown in Figure 52.

Table 45 — Associations of *healthcare investigation*

Specialization of		**Generalization of**		
healthcare activity element				
Association from		**Association name**	**Association to**	
0..*	healthcare investigation	clarifies	1	health state
0..*	healthcare investigation	reveals	0..*	health condition

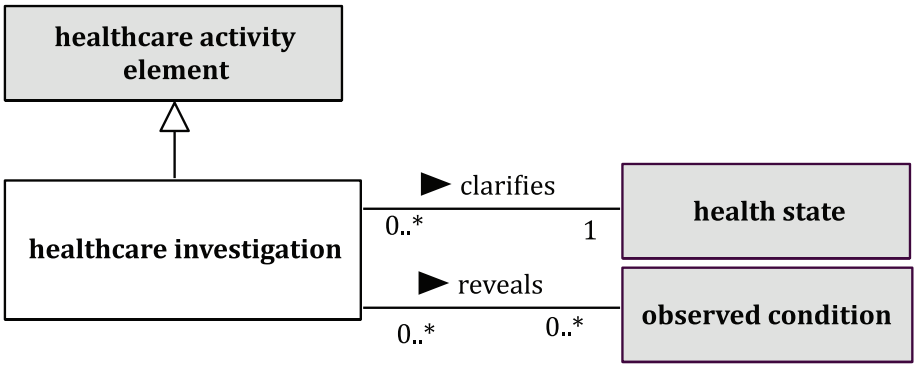

Figure 52 — Healthcare investigation (UML representation)

7.2.7.3 Healthcare activity management

Term: *healthcare activity management*

Definition: *healthcare activity element* during which the status of *healthcare activities* in a *care plan* are changed

NOTE Examples statuses for *healthcare activities* are; planned, scheduled, resource allocated, ongoing, performed/finished, evaluated.

Table 46 lists the associations of this concept; a UML representation of the concept is shown in Figure 53.

Table 46 — Associations of *healthcare activity management*

Specialization of			**Generalization of**		
healthcare activity element					
Component of			**Aggregation of**		
			0..*	healthcare planning	
Association from		**Association name**	**Association to**		
0..*	healthcare activity management	manages	1..*	healthcare activity	
0..*	healthcare activity management	changes statuses of healthcare activities in	1	care plan	

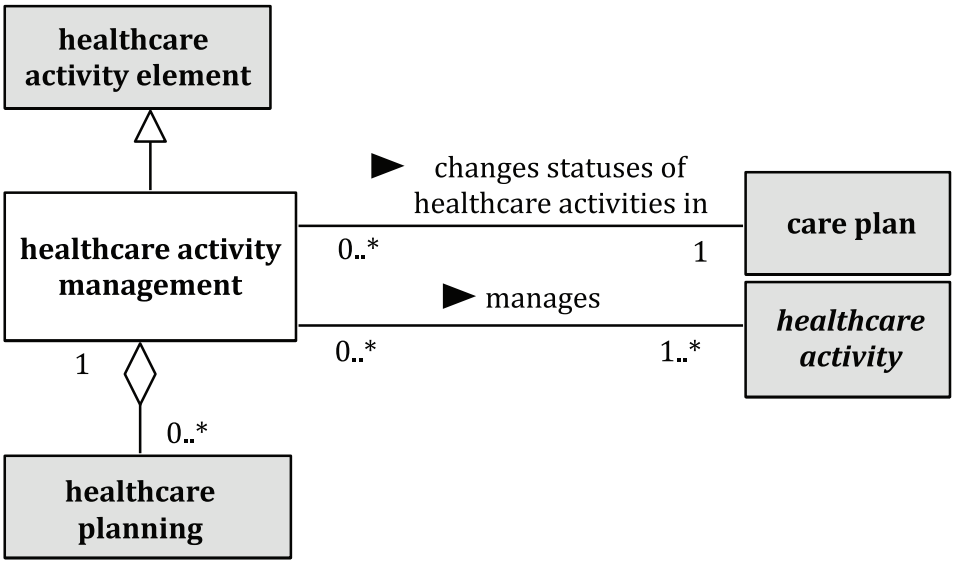

Figure 53 — Healthcare activity management (UML representation)

7.2.7.4 Healthcare assessment

Term: *healthcare assessment*

Definition: *healthcare activity element* where an opinion related to *health conditions* and/or *healthcare activities* is formed

Table 47 lists the associations of this concept; a UML representation of the concept is shown in Figure 54.

Table 47 — Associations of *healthcare assessment*

Specialization of	Generalization of
healthcare activity element	healthcare needs assessment

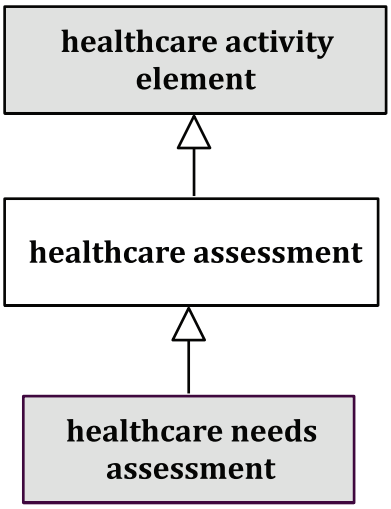

Figure 54 — Healthcare assessment (UML representation)

7.2.7.5 Healthcare needs assessment

Term: *healthcare needs assessment*

Definition: *healthcare assessment* during which a *healthcare professional* considers a *subject of care*'s *health need* and determines the *needed healthcare activity*

NOTE 1 A *healthcare needs assessment* precedes *healthcare planning*.

NOTE 2 *Healthcare needs assessments* should be performed in a dialogue with the *subject of care*. The responsibility for a *healthcare needs assessment* is held by a *healthcare professional*.

NOTE 3 The *subjects of care* interact with *healthcare professionals* in *healthcare needs assessments* and also describe their opinions on which *healthcare activities* should be asked for in a demand for care.

Table 48 lists the associations of this concept; a UML representation of the concept is shown in Figure 55.

Table 48 — Associations of *healthcare needs assessment*

Specialization of		**Generalization of**		
healthcare assessment				
Association from		**Association name**	**Association to**	
0..*	healthcare needs assessment	precedes	0..1	healthcare planning
0..*	subject of care desire	is considered during	1..*	healthcare needs assessment
1..*	healthcare professional	performs	0..*	healthcare needs assessment
0..*	healthcare needs assessment	identifies	0..*	needed healthcare activity
1	health need	is considered during	0..*	healthcare needs assessment

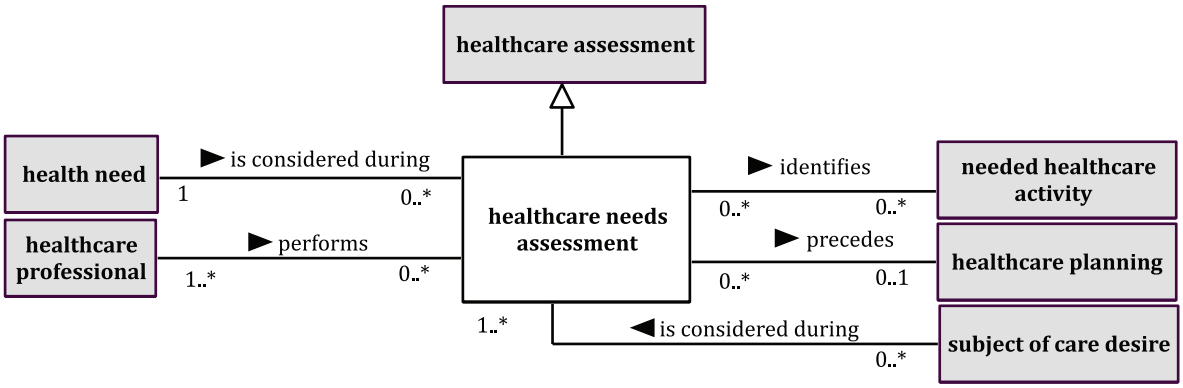

Figure 55 — Healthcare needs assessment (UML representation)

7.2.7.6 Healthcare planning

Term: *healthcare planning*

Synonym: care planning

Definition: element of *healthcare activity management* where a *care plan* is created or modified

Table 49 lists the associations of this concept; a UML representation of the concept is shown in Figure 56.

Table 49 — Associations of *healthcare planning*

Component of		**Aggregation of**	
1	healthcare activity management		

Association from		**Association name**	**Association to**	
0..*	healthcare planning	is based upon	0..*	clinical guideline
0..*	care plan	is result of	1..*	healthcare planning
0..*	healthcare needs assessment	precedes	0..1	healthcare planning

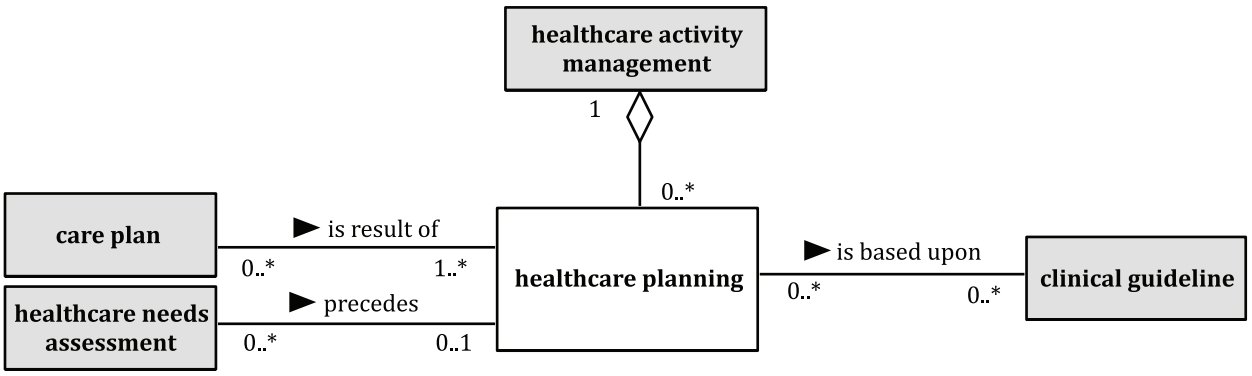

Figure 56 — Healthcare planning (UML representation)

7.2.7.7 Healthcare evaluation

Term: *healthcare evaluation*

Definition: *healthcare activity element* where aspects of at least one other *healthcare activity element* is evaluated

NOTE 1 *Healthcare evaluation* may be performed by all kinds of *healthcare actors*, including the *subject of care*.

NOTE 2 See also *clinical process outcome evaluation*.

Table 50 lists the associations of this concept; a UML representation of the concept is shown in Figure 57.

Table 50 — Associations of *healthcare evaluation*

Specialization of	**Generalization of**
healthcare activity element	healthcare process evaluation
	clinical process outcome evaluation

Association from		**Association name**	**Association to**	
0..*	healthcare evaluation	evaluates aspects of	1..*	healthcare activity

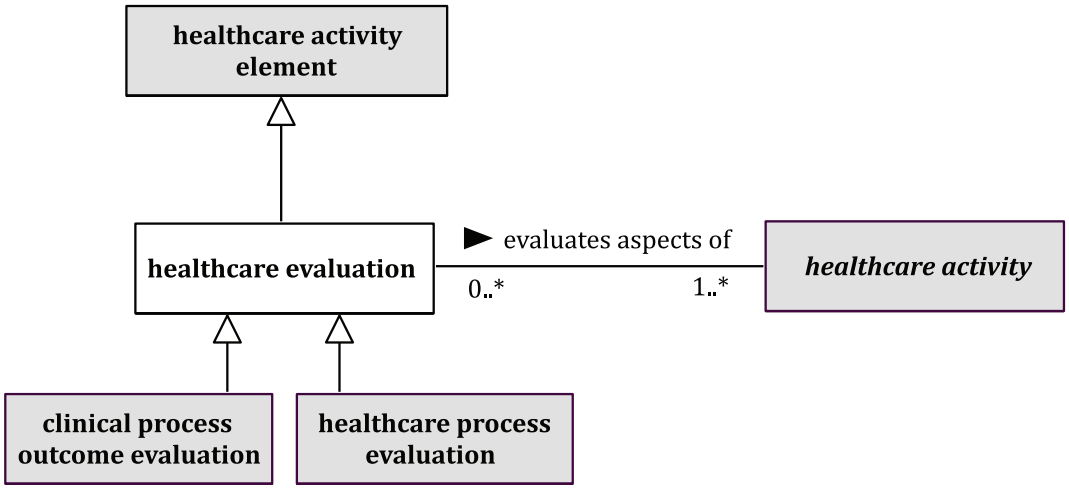

Figure 57 — Healthcare evaluation (UML representation)

7.2.7.7.1 Healthcare process evaluation

Term: *healthcare process evaluation*

Definition: *healthcare evaluation* where *healthcare processes* are systematically assessed against requirements

NOTE 1 The outputs of *clinical processes* are evaluated in a *clinical process outcome evaluation*.

NOTE 2 Requirements are defined as a combination of needs and expectations that are stated, generally implied or obligatory. The needs can be represented by, for example, *target conditions*, goals for resource consumption, compliance to guidelines, etc. The expectations can be represented by the perceptions of the outcomes from each of the involved *healthcare actor's* perspective (i.e. *subject of care* and *healthcare professionals*).

Table 51 lists the associations of this concept; a UML representation of the concept is shown in Figure 58.

Table 51 — Associations of *healthcare process evaluation*

Specialization of	**Generalization of**
healthcare evaluation	

Association from		**Association name**	**Association to**	
0..*	healthcare process evaluation	evaluates	1..*	healthcare process

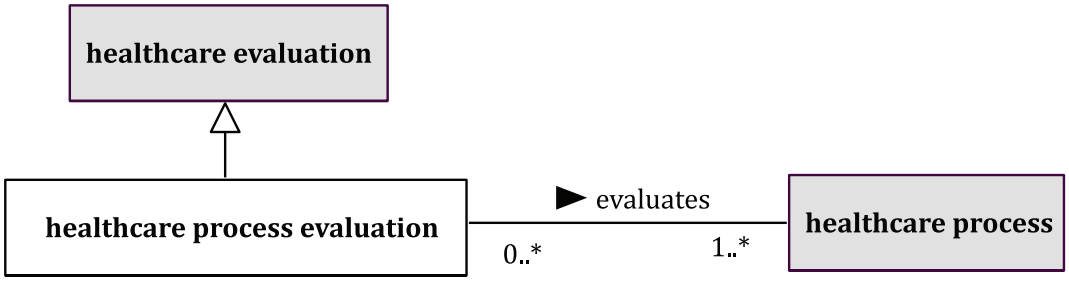

Figure 58 — Healthcare process evaluation (UML representation)

7.2.7.7.2 Clinical process outcome evaluation

Term: *clinical process outcome evaluation*

Definition: *healthcare evaluation* where the effects of a *clinical process* on a *health state* are assessed against the *target condition* and/or a *health condition* representing the *input health state*

NOTE 1 The *subject of care* and *healthcare professionals* are the main contributors to a *clinical process outcome* evaluation.

NOTE 2 The *target condition* represents a requirement for the *clinical process*.

Table 52 lists the associations of this concept; a UML representation of the concept is shown in Figure 59.

Table 52 — Associations of *clinical process outcome evaluation*

Specialization of		**Generalization of**		
healthcare evaluation				
Association from		**Association name**	**Association to**	
0..*	clinical process outcome evaluation	evaluates outcome of	1	clinical process
1..*	target condition	is input to	0..*	clinical process outcome evaluation
0..*	resultant condition	is input to	0..*	clinical process outcome evaluation

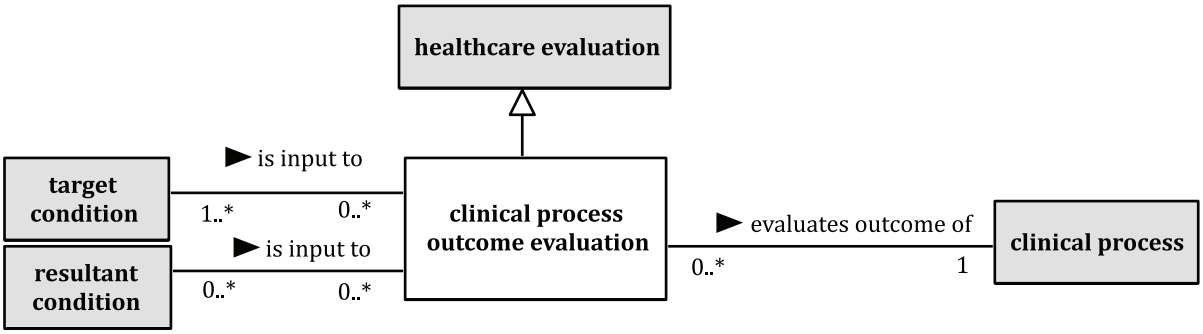

Figure 59 — Clinical process outcome evaluation (UML representation)

7.2.7.8 Healthcare documenting

Term: *healthcare documenting*

Definition: *healthcare activity element* where *health records* are created or maintained

Table 53 lists the associations of this concept; a UML representation of the concept is shown in Figure 60.

Table 53 — Associations of *healthcare documenting*

Specialization of		**Generalization of**		
healthcare activity element				
Association from		**Association name**	**Association to**	
1..*	healthcare documenting	maintains	1..*	health record

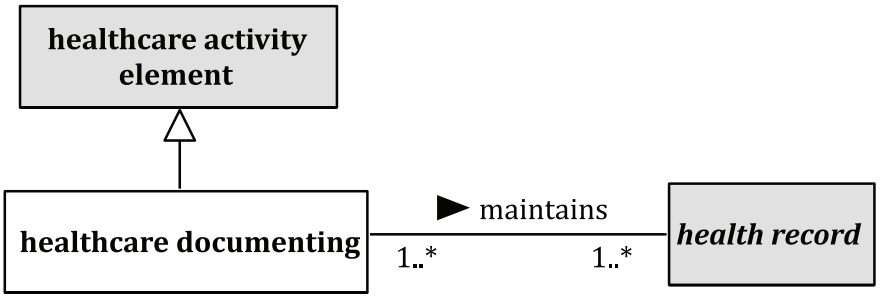

Figure 60 — Healthcare documenting (UML representation)

7.2.7.9 Healthcare communication

Term: *healthcare communication*

Definition: *healthcare activity element* where at least two *healthcare actors* communicate

Table 54 lists the associations of this concept; a UML representation of the concept is shown in Figure 61.

Table 54 — Associations of *healthcare communication*

Specialization of	Generalization of
healthcare activity element	

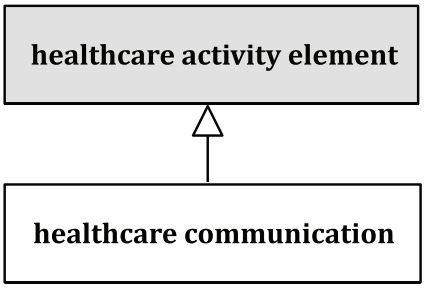

Figure 61 — Healthcare communication (UML representation)

7.2.8 Automated healthcare

Term: *automated healthcare*

Definition: method of delivering healthcare initiated by a responsible *healthcare actor* and thereafter delivered automatically by an *automatic medical device*

NOTE A*utomated healthcare* is not a *healthcare activity* in its own right since the *automatic medical device* doesn't have the capacity to be responsible. It is the *healthcare actor* who initiates and reviews the *automated healthcare* that is responsible for safe use of the *automatic medical device.*

EXAMPLE Activities performed by the machine during a long term Electrocardiography ("Holter recording") programme, implanted cardiac defibrillator.

Table 55 lists the associations of this concept; a UML representation of the concept is shown in Figure 62.

Table 55 — Associations of *automated healthcare*

Association from		Association name	Association to	
0..*	automated healthcare	initiated during	1	healthcare activity
0..*	automated healthcare	reviewed during	0..*	healthcare activity
0..*	automated healthcare	terminated during	0..1	healthcare activity
0..*	automated healthcare	results in	0..*	non-ratified healthcare information
1..*	healthcare actor	is responsible for	0..*	automated healthcare
1	automatic medical device	delivers	0..*	automated healthcare

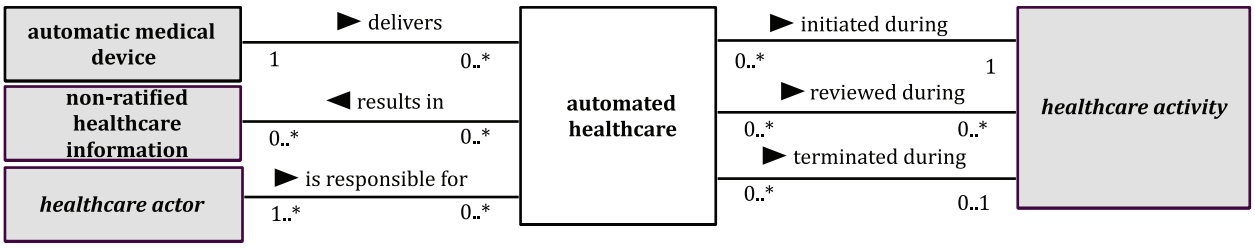

Figure 62 — Automated healthcare (UML representation)

7.2.9 Healthcare resource

Term: *healthcare resource*

Definition: resource needed to perform *healthcare activities*

NOTE As a *healthcare process* develops, the *healthcare resources* follow a life cycle. Examples of steps of such a life cycle are: 'available', 'booked', 'provided', "in use', 'consumed', etc.

EXAMPLES *Healthcare professional* on duty, operation theatre, instruments ready to use, consultation rooms, bed in a ward, prepared medicinal products, Electrocardiography-device, blood sample, donated kidney, etc.

Table 56 lists the associations of this concept; a UML representation of the concept is shown in Figure 63.

Table 56 — Associations of *healthcare resource*

Specialization of	Generalization of
resource	healthcare personnel
	point of care
	medicinal product
	medical device

Association from		Association name	Association to	
1..*	healthcare activity	requires	1..*	healthcare resource
1..*	healthcare resource management	direct and control the supply and use of	1..*	healthcare resource
0..*	healthcare funds	is funding	0..*	healthcare resource

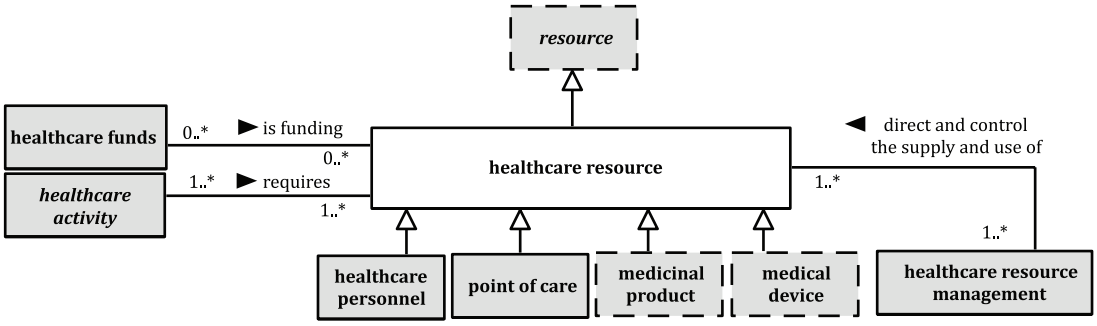

Figure 63 — Healthcare resource (UML representation)

7.2.9.1 Point of care

Term: *point of care*

Definition: location where direct *healthcare activities* are performed

NOTE Location refers to the geographical location of the *subject of care*; not the body area of the *subject of care* that the treatment is applied to.

EXAMPLES Surgery room, ward, ambulance, road side, home of the *subject of care*, school, etc.

Table 57 lists the associations of this concept; a UML representation of the concept is shown in Figure 64.

Table 57 — Associations of *point of care*

Specialization of	Generalization of
healthcare resource	

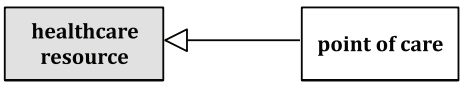

Figure 64 — Point of care (UML representation)

7.2.9.2 Automatic medical device

Term: *automatic medical device*

Definition: *medical device* capable of performing automated *healthcare activities*

NOTE In EN 13940–1:2007 the concept *healthcare device* was a specialization of *healthcare actor* and defined as 'device or equipment, possibly including a piece of software, involved in the provision of *health care activities*'.

EXAMPLES A specific identifiable Electrocardiography machine, electronic blood-sugar monitor.

Table 58 lists the associations of this concept; a UML representation of the concept is shown in Figure 65.

Table 58 — Associations of *automatic medical device*

Specialization of	Generalization of
medical device	

Table 58 *(continued)*

Association from		Association name	Association to	
1	automatic medical device	delivers	0..*	automated healthcare

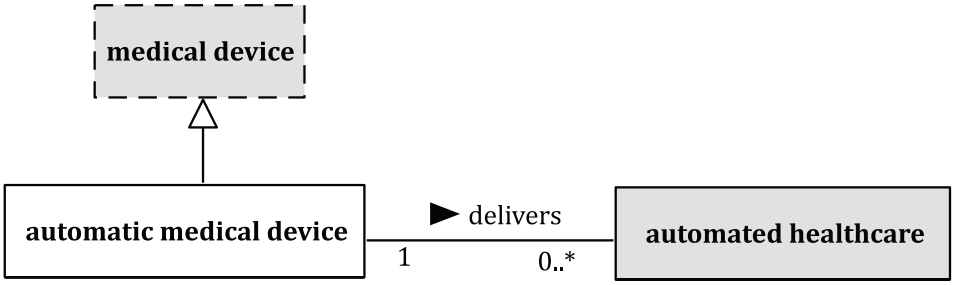

Figure 65 — Automatic medical device (UML representation)

7.2.9.3 Healthcare resource management

Term: *healthcare resource management*

Definition: activities to direct and control the supply and use of the *healthcare resources* required to perform *healthcare activities*

Table 59 lists the associations of this concept; a UML representation of the concept is shown in Figure 66.

Table 59 — Associations of *healthcare resource management*

Association from		Association name	Association to	
1..*	healthcare resource management	direct and control the supply and use of	1..*	healthcare resource
1..*	healthcare activity	requires	0..*	healthcare resource management
1	healthcare provider	performs	0..*	healthcare resource management

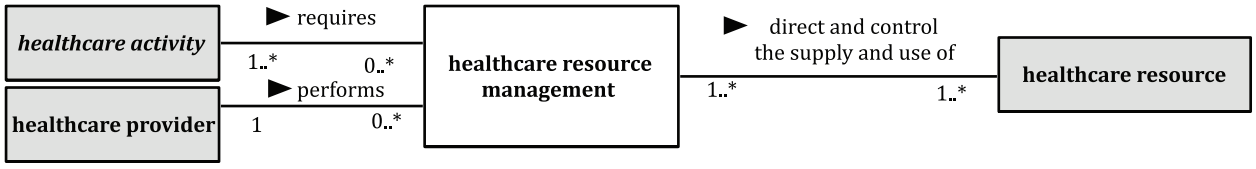

Figure 66 — Healthcare resource management (UML representation)

7.2.10 Healthcare funds

Term: *healthcare funds*

Synonym: care funds

Definition: resource provided for funding healthcare delivery

NOTE Funds may be provided by, for example, a health insurance fund, a governmental agency, a national or local authority, a welfare programme, the subject of care or any other person or organization having a role in the funding of healthcare.

Table 60 lists the associations of this concept; a UML representation of the concept is shown in Figure 67.

Table 60 — Associations of *healthcare funds*

Specialization of		**Generalization of**		
resource				
Association from		**Association name**	**Association to**	
0..*	healthcare	is financed by	0..*	healthcare funds
0..*	healthcare actor	provides	0..*	healthcare funds
0..*	healthcare funds	is funding	0..*	healthcare resource

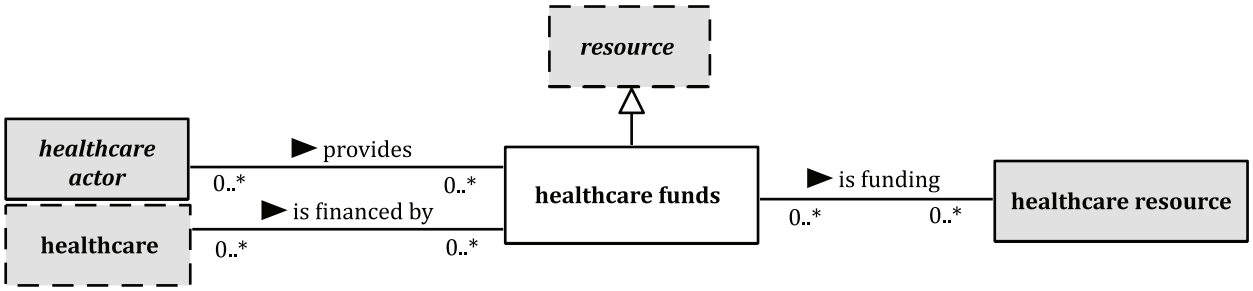

Figure 67 — Healthcare funds (UML representation)

8 Concepts related to process

8.1 General

A model showing the associations between the process related concepts and the other concepts defined in this International Standard is shown in Figure 68. For further detail about the diagram notation, please refer to 0.7 in the Introduction.

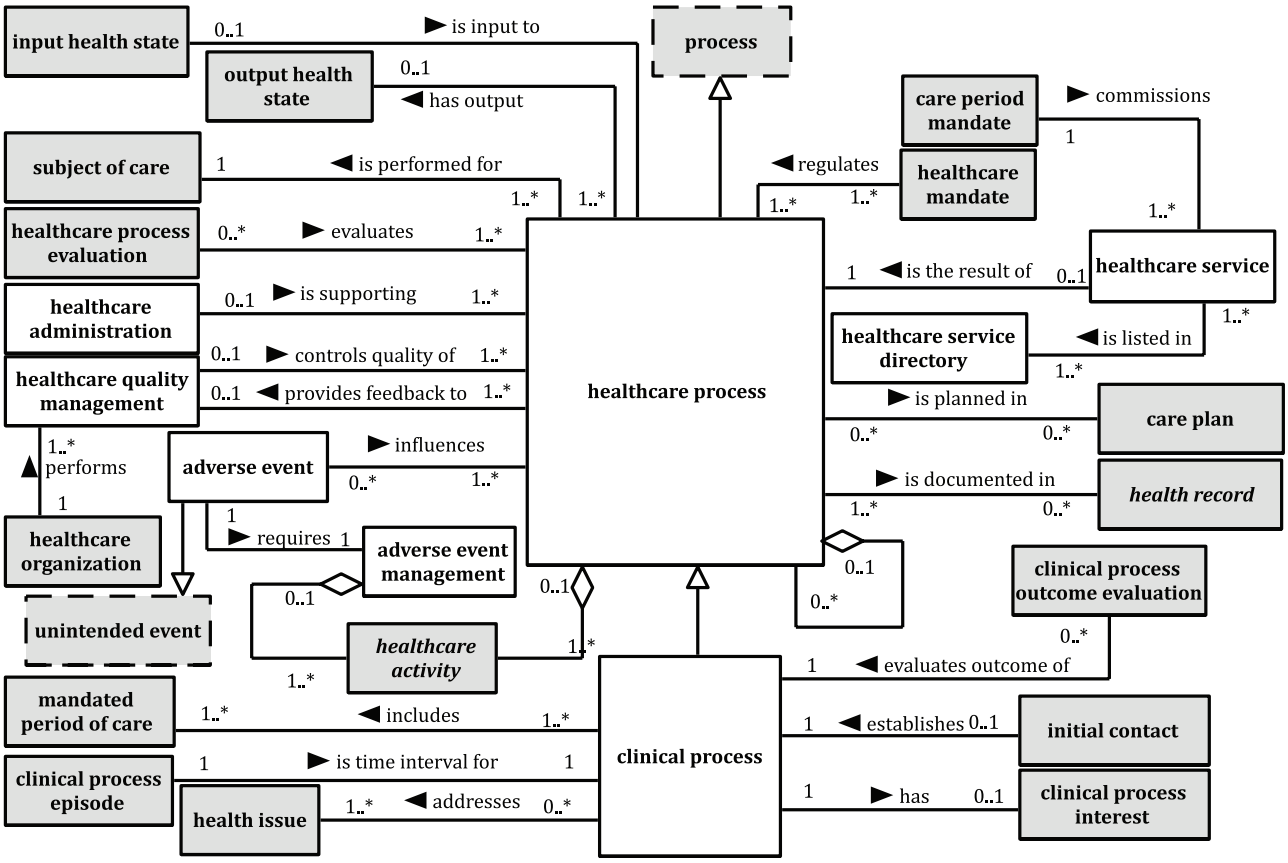

Figure 68 — Comprehensive UML diagram of concepts related to process

8.2 Healthcare process

Term: *healthcare process*

Synonym: care process

Definition: set of interrelated or interacting *healthcare activities* which transforms inputs into outputs

NOTE 1 The main type of *healthcare process* is the *clinical process* that has a health state as input and output and includes all activities in relation to one or more specified *health issues*.

NOTE 2 A *healthcare process* is not by definition restricted to one *healthcare provider* or any other organizational unit borders.

Table 61 lists the associations of this concept; a UML representation of the concept is shown in Figure 69.

Table 61 — Associations of *healthcare process*

Specialization of			**Generalization of**		
Process			clinical process		
Component of			**Aggregation of**		
0..1	healthcare process		1..*	healthcare activity	
			0..*	healthcare process	
Association from		**Association name**	**Association to**		
1..*	healthcare process	is performed for	1	subject of care	
0..*	healthcare process	is planned in	0..*	care plan	
0..*	healthcare process evaluation	evaluates	1..*	healthcare process	
1..*	healthcare process	is documented in	0..*	health record	
1..*	healthcare process	has output	0..1	output health state	
1..*	healthcare process	provides feedback to	0..1	healthcare quality management	
1..*	healthcare mandate	regulates	1..*	healthcare processes	
0..1	input health state	is input to	1	healthcare process	
0..1	healthcare administration	is supporting	1..*	healthcare process	
0..1	healthcare quality management	controls quality of	1..*	healthcare process	
0..*	adverse event	influences	1..*	healthcare process	
0..1	healthcare service	is the result of	1	healthcare process	

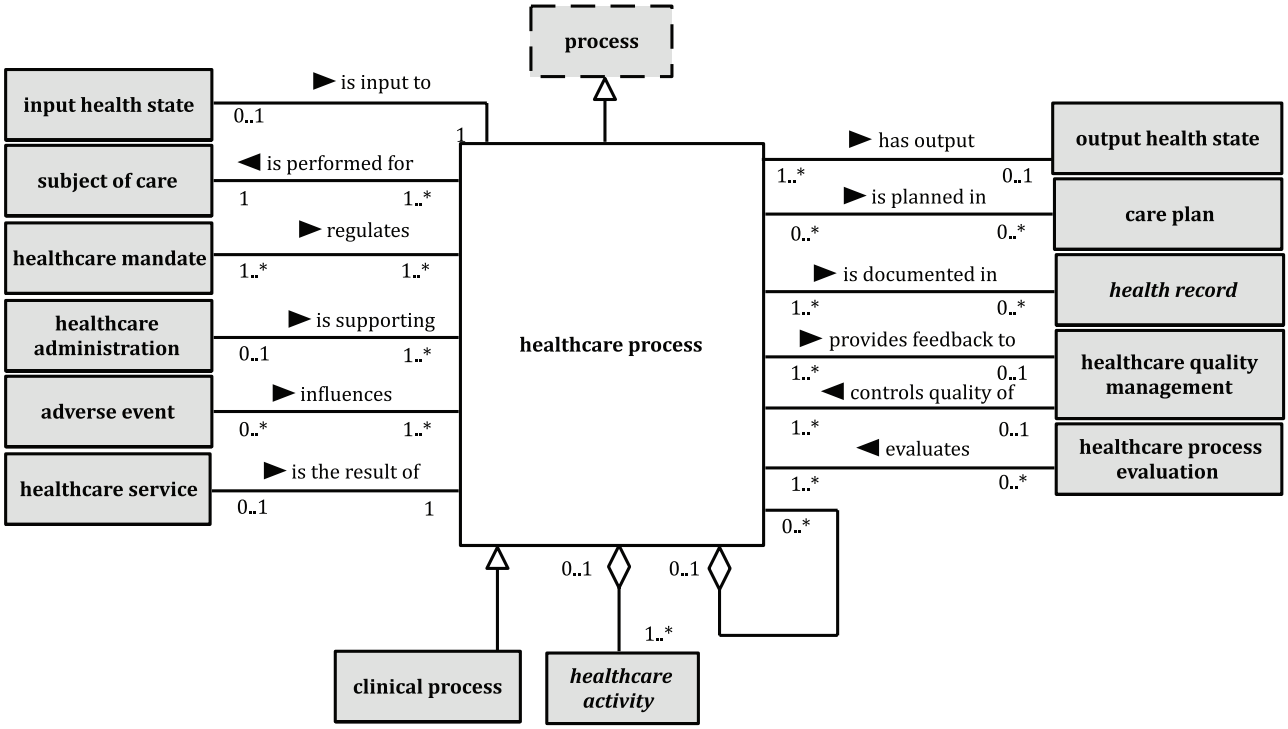

Figure 69 — Healthcare process (UML representation)

8.2.1 Clinical process

Term: *clinical process*

Definition: *healthcare process* encompassing all *healthcare provider activities* and other prescribed *healthcare activities* that addresses identified or specified *health issues*

NOTE 1 As such, a *clinical process* is a set of interrelated or interacting *healthcare activities*, which are performed for a *subject of care* with one or more *health issues*.

NOTE 2 The primary input and output to a *clinical process* is the health state.

NOTE 3 In a *clinical process* a *subject of care* and *healthcare professionals* interact in all types of *healthcare activities*.

NOTE 4 A *clinical process* comprises all kinds of *healthcare activities*, mainly *healthcare provider activities*, but also *self-care activities* as prescribed or recommended by *healthcare professionals*.

NOTE 5 The *clinical process* can be regarded as the key type of *process* to support continuity of care from the perspective of the *subject of care*.

NOTE 6 *Clinical processes* are the essential, central and most important type of *healthcare processes*.

NOTE 7 A relevant distinction exists between the primary input (the *subject of care's* initial *health state*) and secondary or ancillary inputs (the resources brought in to perform the *clinical process*).

Table 62 lists the associations of this concept; a UML representation of the concept is shown in Figure 70.

Table 62 — Associations of *clinical process*

Specialization of		**Generalization of**		
healthcare process				
Association from		**Association name**	**Association to**	
0..*	clinical process	addresses	1..*	health issue
1..*	clinical process	includes	1..*	mandated period of care
1	clinical process episode	is time interval for	1	clinical process
1	clinical process	has	0..1	clinical process interest
0..*	clinical process outcome evaluation	evaluates outcome of	1	clinical process
0..1	initial contact	establishes	1	clinical process

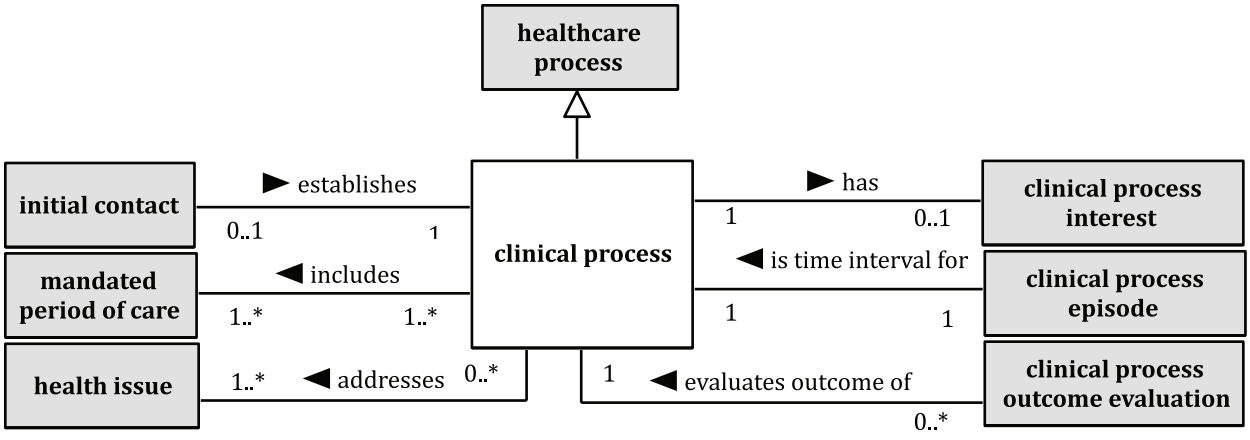

Figure 70 — Clinical process (UML representation)

8.2.2 Healthcare quality management

Term: *healthcare quality management*

Synonym: clinical governance

Definition: coordinated activities to direct and control a *healthcare organization* with regard to quality

NOTE 1 The *clinical processes* are the most important type of *healthcare processes* related to *healthcare quality management*.

NOTE 2 *Healthcare quality management* activities include the establishment of a quality policy, setting quality objectives, the performance of audits, evaluation and a feedback loop for quality improvement, all resulting in quality assurance.

EXAMPLES Direct and control the fulfilment of requirements in quality criteria repositories, changing behaviour of *healthcare professionals*.

Table 63 lists the associations of this concept; a UML representation of the concept is shown in Figure 71.

Table 63 — Associations of *healthcare quality management*

Association from		Association name	Association to	
0..1	healthcare quality management	controls quality of	1..*	healthcare process
1	healthcare organization	performs	1..*	healthcare quality management
1..*	healthcare process	provides feedback to	0..1	healthcare quality management

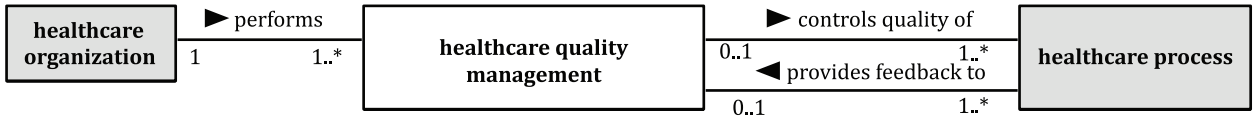

Figure 71 — Healthcare quality management (UML representation)

8.2.3 Healthcare administration

Term: *healthcare administration*

Definition: administrative activities related to *healthcare processes*

NOTE Administrative activities are indirect activities in a *healthcare process* and include support and management.

EXAMPLES Budgeting and resource allocation, organizational structure, non-clinical documentation, administrative activity management, resource management, etc.

Table 64 lists the associations of this concept; a UML representation of the concept is shown in Figure 72.

Table 64 — Associations of *healthcare administration*

Association from		Association name	Association to	
0..1	healthcare administration	is supporting	1..*	healthcare process

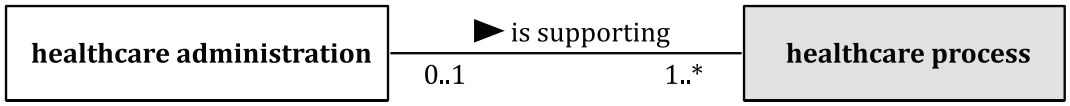

Figure 72 — Healthcare administration (UML representation)

8.2.4 Adverse event

Term: *adverse event*

Definition: unintended event that has negative influence upon *healthcare processes*

NOTE 1 'Iatrogenesis' or 'iatrogeny' is a common cause of *adverse events*.

NOTE 2 *Adverse events* can occur during appropriate *healthcare activities.*

NOTE 3 *Adverse events* may cause harm.

EXAMPLES

An infection acquired during a hospital stay.

A drug may be used as recommended but cause allergic reaction when the drug allergy was not known before the treatment.

An accident in connection to a *healthcare activity* can be an adverse event.

A mishap during correctly performed *healthcare activity* may also be regarded as an adverse event

Table 65 lists the associations of this concept; a UML representation of the concept is shown in Figure 73.

Table 65 — Associations of *adverse event*

Specialization of		**Generalization of**		
unintended event				
Association from		**Association name**	**Association to**	
0..*	adverse event	influences	1..*	healthcare process
1	adverse event	requires	1	adverse event management

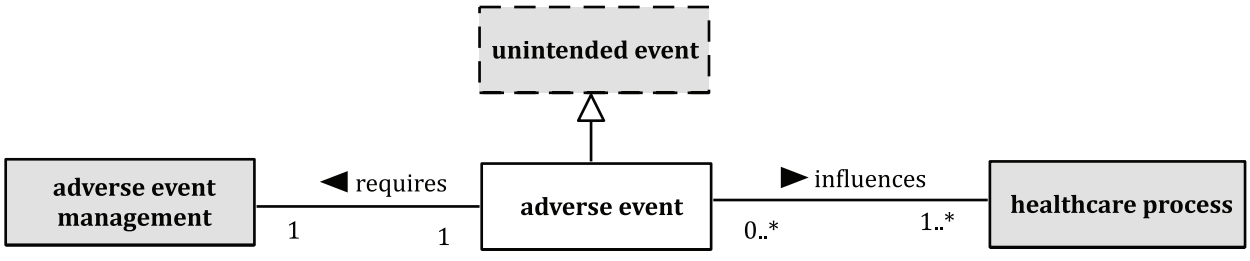

Figure 73 — Adverse event (UML representation)

8.2.5 Adverse event management

Term: *adverse event management*

Definition: set of *healthcare activities* performed in response to an *adverse event*

NOTE The purposes for *adverse event management* are usually two: one is to reverse the effect or minimize the consequences of the *adverse event*, another one is to prevent the kind of *adverse event* in the future.

Table 66 lists the associations of this concept; a UML representation of the concept is shown in Figure 74.

Table 66 — Associations of *adverse event management*

Component of		**Aggregation of**	
		1..*	healthcare activity

Association from		**Association name**	**Association to**	
1	adverse event	requires	1	adverse event management

Figure 74 — Adverse event management (UML representation)

8.2.6 Healthcare service

Term: *healthcare service*

Definition: service that is the result of a *healthcare process*

NOTE Comprehensive h*ealthcare services* intended for specified *health issues* are results of *clinical processes.*

EXAMPLE Diagnostic investigation and result report.

Table 67 lists the associations of this concept; a UML representation of the concept is shown in Figure 75.

Table 67 — Associations of *healthcare service*

Association from		**Association name**	**Association to**	
0..1	healthcare service	is the result of	1	healthcare process
1..*	healthcare service	is listed in	1..*	healthcare service directory
1	care period mandate	commissions	1..*	healthcare service

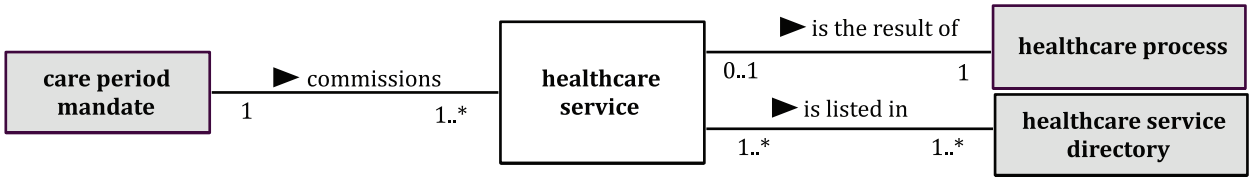

Figure 75 — Healthcare service (UML representation)

8.2.7 Healthcare service directory

Term: *healthcare service directory*

Definition: Directory of the types of *healthcare services* offered by one or more *healthcare providers*

Table 68 lists the associations of this concept; a UML representation of the concept is shown in Figure 76.

Table 68 — Associations of *healthcare service directory*

Association from		Association name	Association to	
1..*	healthcare service	is listed in	1..*	healthcare service directory

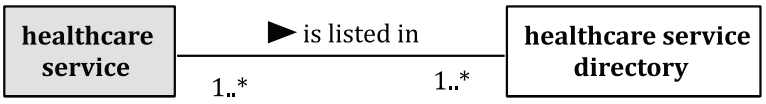

Figure 76 — Healthcare service directory (UML representation)

9 Concepts related to healthcare planning

9.1 General

A model showing the associations between the concepts related to the use of clinical knowledge and decision support in continuity of care and the other concepts defined in this International Standard is shown in Figure 77. For further detail about the diagram notation, please refer to 0.7 in the Introduction.

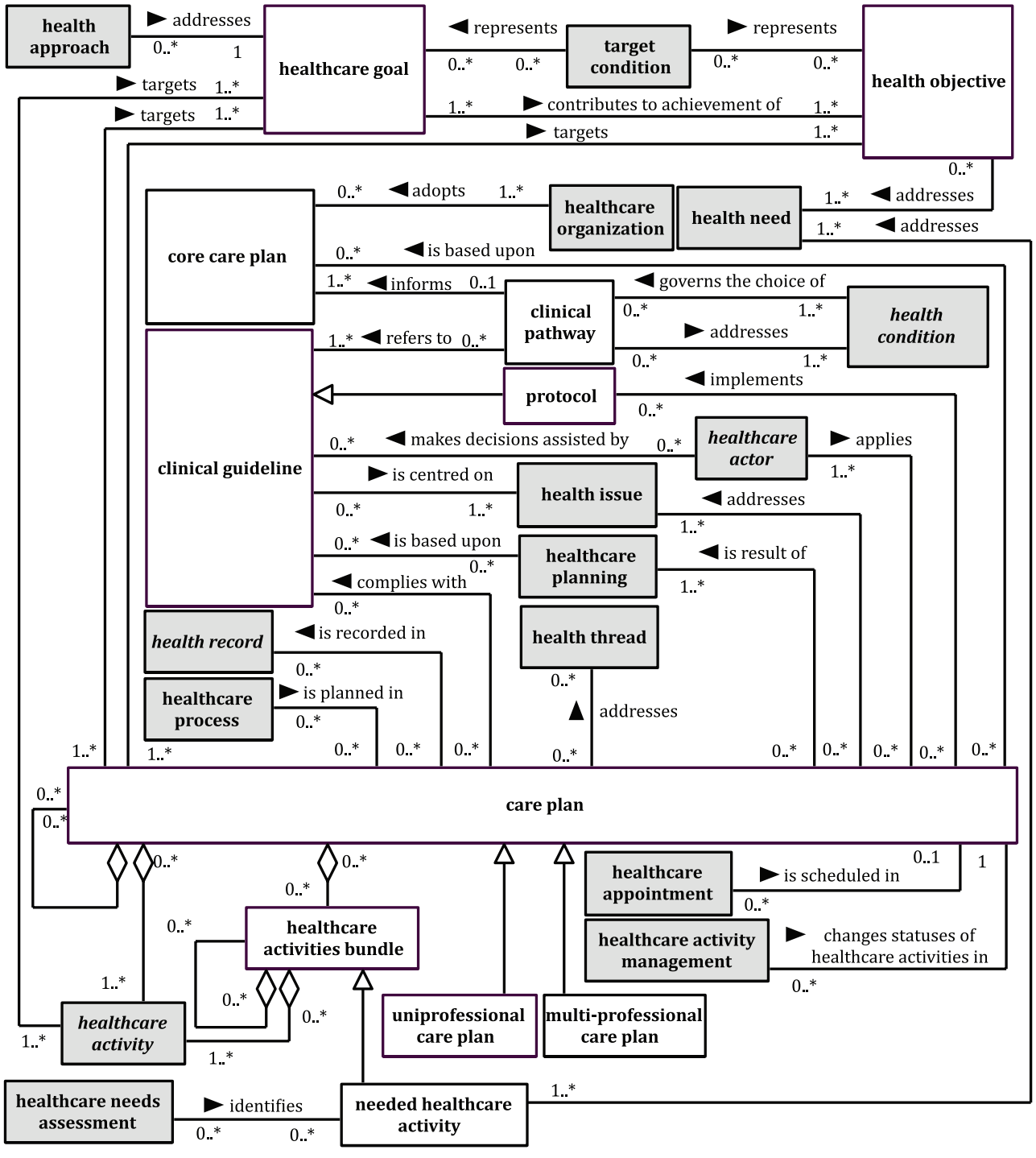

Figure 77 — Comprehensive UML diagram of concepts related to healthcare planning

9.2 Care plan

Term: *care plan*

Synonym: healthcare plan

Deprecated term: programme of care

Definition: 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*

NOTE 1 A *care plan* may be recorded in one or more *health records*.

NOTE 2 A *care plan* could be subdivided from different perspectives by different constraints. One example is *uniprofessional care plan*, for example, a nursing care plan with the constraint of only one specific *healthcare professional* involved. Other examples of specific constraints for a *care plan* are: *care plan* to address one *health issue*, one *health condition*, one *contact*, one *clinical process*, *healthcare activities* to be performed by one *healthcare provider,* etc.

NOTE 3 *Care plans* are reviewed repeatedly during a *healthcare process*, each review based on a new healthcare needs assessment.

NOTE 4 The *healthcare activities* in a *care plan* follow a life cycle. Examples of statuses of such a life cycle are: 'planned', 'performed', 'cancelled', etc.; all of these statuses are included in the care plan.

NOTE 5 In EN 13940–1:2007 programme of care was the preferred term for this concept.

EXAMPLE A *care plan* for retinopathy in diabetics by video-retinoscopy, which involves the GP and an ophthalmologist and implies specific mobile equipment (video-retinoscope) with a camera.

Table 69 lists the associations of this concept; a UML representation of the concept is shown in Figure 77.

Table 69 — Associations of *care plan*

Specialization of	**Generalization of**
	uniprofessional care plan
	multi-professional care plan

Component of		**Aggregation of**	
0..*	care plan	0..*	care plan
		1..*	healthcare activity
		0..*	healthcare activities bundle

Association from		**Association name**	**Association to**	
0..*	care plan	complies with	0..*	clinical guideline
0..*	care plan	implements	0..*	protocol
0..*	care plan	is based upon	0..*	core care plan
0..*	care plan	addresses	1..*	health issue
0..*	care plan	addresses	0..*	health thread
1..*	care plan	targets	1..*	health objective
1..*	care plan	targets	1..*	healthcare goal
0..*	care plan	is result of	1..*	healthcare planning
1..*	healthcare actor	applies	0..*	care plan
0..*	healthcare process	is planned in	0..*	care plan
0..*	healthcare appointment	is scheduled in	0..1	care plan

Table 69 *(continued)*

0..*	healthcare activity management	changes statuses of healthcare activities in	1	care plan
0..*	care plan	is recorded in	0..*	health record

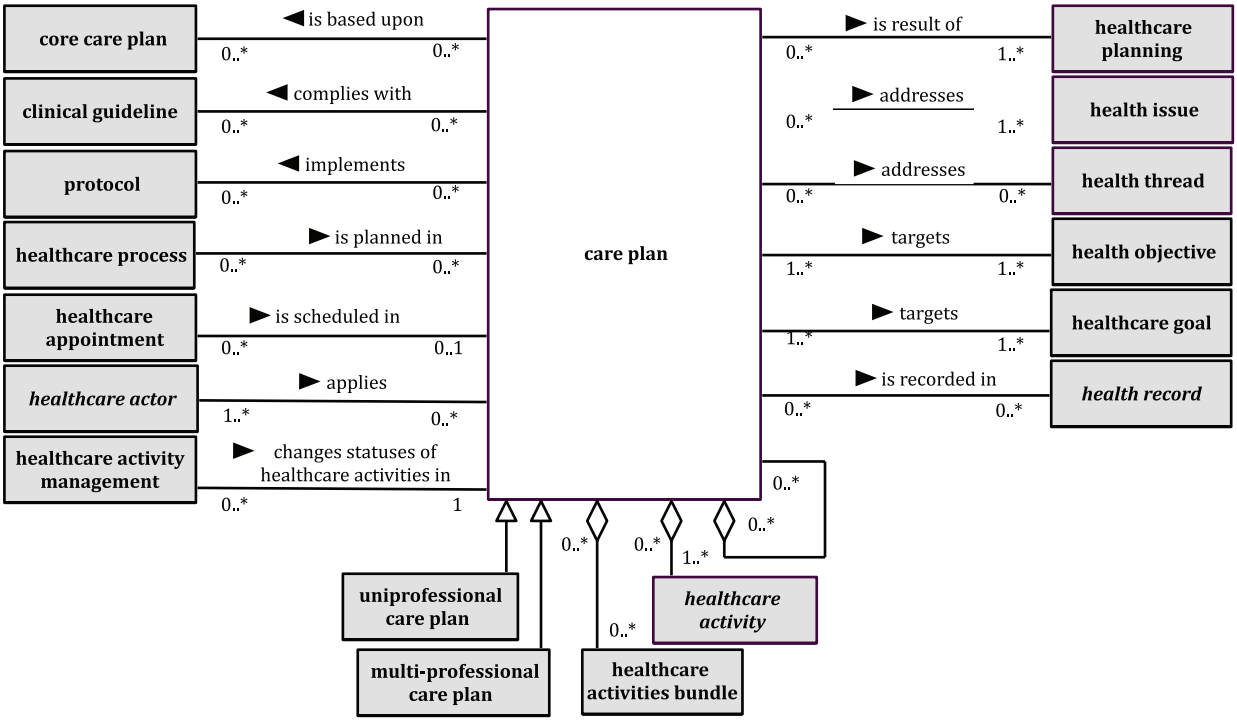

Figure 78 — Care plan (UML representation)

9.2.1 Uniprofessional care plan

Term: *uniprofessional care plan*

Synonym: uniprofessional healthcare plan

Deprecated term: care plan

Definition: *care plan* limited to those *healthcare provider activities* performed by *healthcare professionals* having the same *healthcare professional entitlement*

NOTE In EN 13940–1:2007 care plan was the preferred term for this concept.

EXAMPLE A nursing care plan.

Table 70 lists the associations of this concept; a UML representation of the concept is shown in Figure 79.

Table 70 — Associations of *uniprofessional care plan*

Specialization of	Generalization of
care plan	

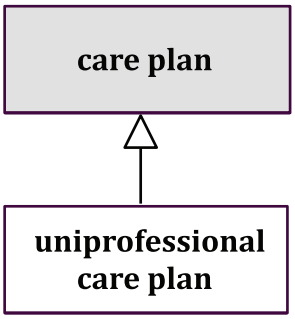

Figure 79 — Uniprofessional care plan (UML representation)

9.2.2 Multi-professional care plan

Term: *multi-professional care plan*

Synonyms: multi-professional healthcare plan, multi-disciplinary care plan

Definition: *care plan* encompassing *healthcare provider activities* performed by *healthcare professionals* having different *healthcare professional entitlements*

Table 71 lists the associations of this concept; a UML representation of the concept is shown in Figure 80.

Table 71 — Associations of *multi-professional care plan*

Specialization of	Generalization of
care plan	

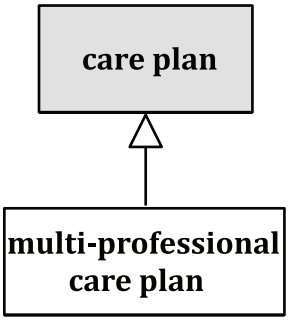

Figure 80 — Multi-professional care plan (UML representation)

9.2.3 Core care plan

Term: *core care plan*

Synonym: standardized care plan

Definition: reusable content and structure for a potential *care plan* for a specified set of circumstances

NOTE 1 A *core care plan* is usually based upon knowledge in *clinical guidelines* (including protocols).

NOTE 2 *Core care plans* can be applied in care planning as a *clinical process* management method.

NOTE 3 A *core care plan* may include advanced formulated schemes for recommended *healthcare activities.*

Table 72 lists the associations of this concept; a UML representation of the concept is shown in Figure 81.

Table 72 — Associations of *core care plan*

Association from		Association name	Association to	
0..1	clinical pathway	informs	1..*	core care plan
1..*	healthcare organization	adopts	0..*	core care plan
0..*	care plan	is based upon	0..*	core care plan

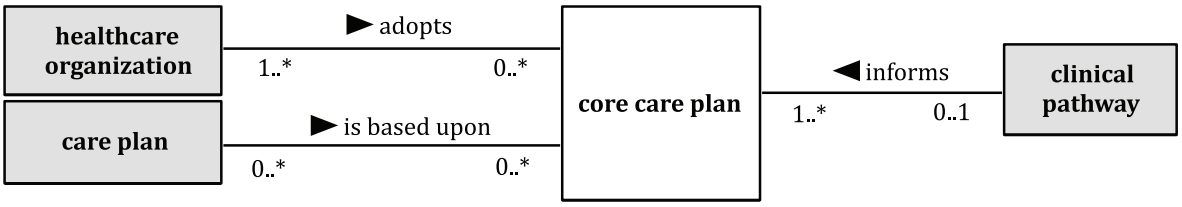

Figure 81 — Core care plan (UML representation)

9.2.4 Clinical guideline

Term: *clinical guideline*

Synonym: care guideline

Definition: 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 *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.

NOTE 2 *Clinical guidelines* should be structured and contain standard criteria and indicators for measurement.

EXAMPLES *Clinical guidelines* related to hypertension, diabetes, pregnancy follow-up, Caesarean section; pressure area management, exercise programmes, social intervention programmes for people with a learning disability

Table 73 lists the associations of this concept; a UML representation of the concept is shown in Figure 82.

Table 73 — Associations of *clinical guideline*

Specialization of	Generalization of
	protocol

Association from		Association name	Association to	
0..*	clinical guideline	is centred on	1..*	health issue
0..*	clinical pathway	refers to	1..*	clinical guideline
0..*	healthcare actor	makes decisions assisted by	0..*	clinical guideline
0..*	healthcare planning	is based upon	0..*	clinical guideline
0..*	care plan	complies with	0..*	clinical guideline

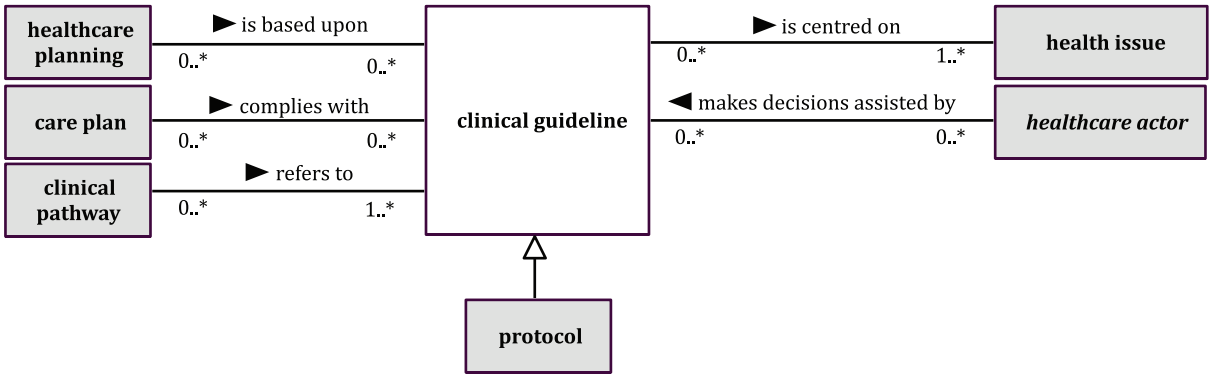

Figure 82 — Clinical guidelines (UML representation)

9.2.4.1 Protocol

Term: *protocol*

Definition: customized *clinical guideline*

NOTE 1 A *protocol* is more precise than a *clinical guideline*.

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

EXAMPLES A *protocol* for a heart failure in an emergency department, a protocol for treatment and follow-up of urinary infections in children in a health centre.

Table 74 lists the associations of this concept; a UML representation of the concept is shown in Figure 83.

Table 74 — Associations of *protocol*

Specialization of	**Generalization of**
clinical guideline	

Association from		**Association name**	**Association to**	
0..*	care plan	implements	0..*	protocol

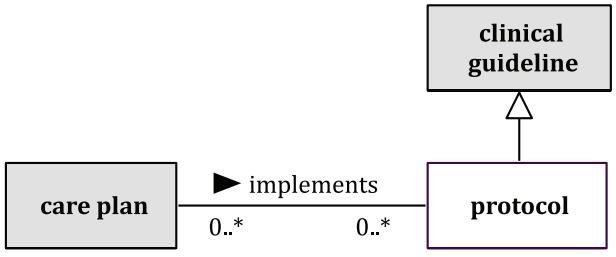

Figure 83 — Protocol (UML representation)

9.2.4.2 Clinical pathway

Term: *clinical pathway*

Synonyms: care pathway, care map, pathway of care

Definition: pathway for the *healthcare activities* informing the content of *core care plans*

NOTE 1 The concept *clinical pathway* includes subtypes, for example, 'integrated care pathways', 'multidisciplinary pathways of care', 'collaborative care pathways'.

NOTE 2 *Clinical pathways* are designed to support *healthcare administration* and *healthcare resource management*. They provide detailed guidance for each stage in the management of a patient (treatments, interventions, etc.).

Table 75 lists the associations of this concept; a UML representation of the concept is shown in Figure 84.

Table 75 — Associations of *clinical pathway*

Association from		Association name	Association to	
0..*	clinical pathway	refers to	1..*	clinical guideline
0..1	clinical pathway	informs	1..*	core care plan
0..*	clinical pathway	addresses	1..*	health condition
1..*	health condition	governs the choice of	0..*	clinical pathway

Figure 84 — Clinical pathway (UML representation)

9.2.5 Health objective

Term: *health objective*

Synonym: intended outcome

Definition: desired ultimate achievement of a *healthcare process* addressing *health needs*

NOTE A *health objective* could be expressed as one or several *target conditions* to be reached within a specified date and time.

EXAMPLES

To increase the survival of a *subject of care* with breast cancer in a breast cancer screening programme.

To reduce a *subject of care* risk of morbidity and mortality from tobacco related diseases in a smoking cessation programme.

To decrease a *subject of care* risk of secondary effects to diabetes

Table 76 lists the associations of this concept; a UML representation of the concept is shown in Figure 85.

Table 76 — Associations of *health objective*

Association from		Association name	Association to	
0..*	health objective	addresses	1..*	health need
1..*	healthcare goal	contributes to achievement of	1..*	health objective

Table 76 *(continued)*

0..*	target condition	represents	0..*	health objective
1..*	care plan	targets	1..*	health objective

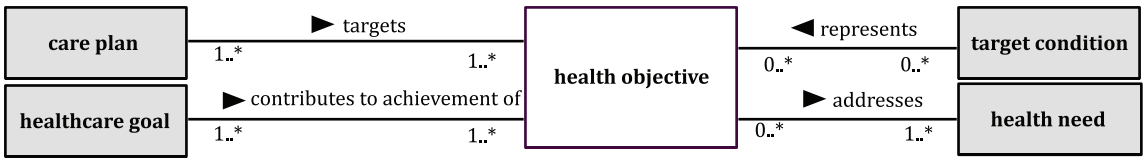

Figure 85 — Health objective (UML representation)

9.2.6 Healthcare goal

Term: *healthcare goal*

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

NOTE A *healthcare goal* could be expressed as one or several *target conditions* to be reached within a specified date and time.

EXAMPLES

To increase the *subject of care's* adherence to the treatment in a hypertension programme. To stabilize the *subject of care's* systolic and diastolic pressure in a hypertension programme.

To increase the *subject of care's* knowledge of their disease through an educational programme for diabetics.

Table 77 lists the associations of this concept; a UML representation of the concept is shown in Figure 86.

Table 77 — Associations of *healthcare goal*

Association from		Association name	Association to	
1..*	healthcare goal	contributes to achievement of	1..*	health objective
1..*	healthcare activity	targets	1..*	healthcare goal
1..*	care plan	targets	1..*	healthcare goal
0..*	target condition	represents	0..*	healthcare goal
0..*	health approach	addresses	1	healthcare goal

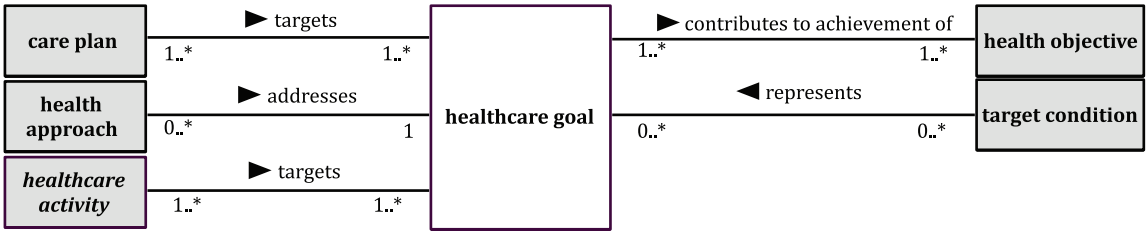

Figure 86 — Healthcare goal (UML representation)

9.2.7 Healthcare activities bundle

Term: *healthcare activities bundle*

Definition: set of *healthcare activities*

NOTE A healthcare activity bundle may be delineated using a health thread comprising healthcare activities.

EXAMPLE All *healthcare activities* provided to a *subject of care* in provision of, during and in the aftermath of a planned surgical operation, in relation to that operation.

Table 78 lists the associations of this concept; a UML representation of the concept is shown in Figure 87.

Table 78 — Associations of *healthcare activities bundle*

Specialization of		**Generalization of**	
		needed healthcare activity	
Component of		**Aggregation of**	
0..*	healthcare activities bundle	0..*	healthcare activities bundle
0..*	care plan	1..*	healthcare activity

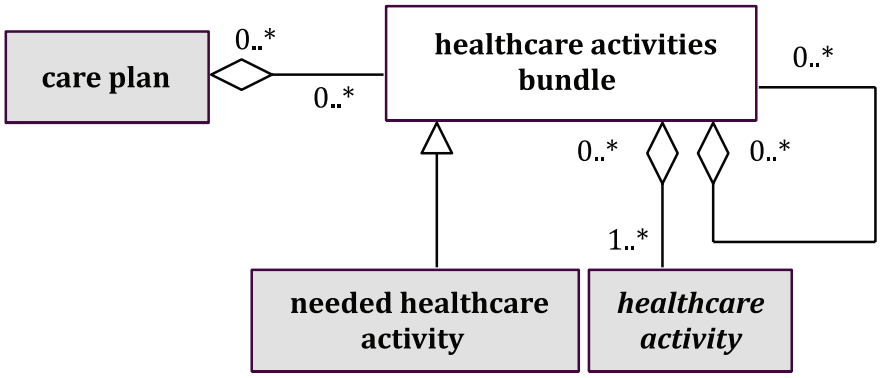

Figure 87 — Healthcare activities bundle (UML representation)

9.2.8 Needed healthcare activity

Term: *needed healthcare activity*

Synonyms: needed care activity, healthcare need, care need

Definition: *healthcare activities bundle* which includes those *healthcare activities* assessed as needed to address specified *health need*

NOTE 1 *Needed healthcare activity* is the *healthcare activity* that is assessed by *healthcare professionals* to be motivated/indicated by the *health need*.

NOTE 2 *Needed healthcare activity* is the outcome of *healthcare needs assessments* performed by *healthcare professionals*. *Needed healthcare activity* can be identified by any mandated *healthcare professional* performing *healthcare needs assessment* for a subject of care.

NOTE 3 *Needed healthcare activity* is managed in a *care plan*.

Table 79 lists the associations of this concept; a UML representation of the concept is shown in Figure 88.

Table 79 — Associations of *needed healthcare activity*

Specialization of	**Generalization of**
healthcare activities bundle	

Table 79 *(continued)*

Association from		Association name	Association to	
0..*	healthcare needs assessment	identifies	0..*	needed healthcare activity
1..*	needed healthcare activity	addresses	1..*	health need

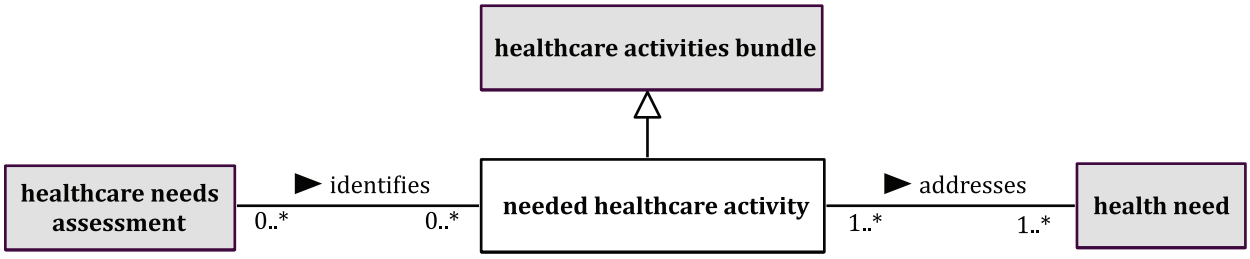

Figure 88 — Needed healthcare activity (UML representation)

10 Concepts related to time

10.1 General

A model showing the associations between the time-related concepts in continuity of care and the other concepts defined in this International Standard is shown in Figure 89. For further detail about the diagram notation, please refer to 0.7 in the Introduction.

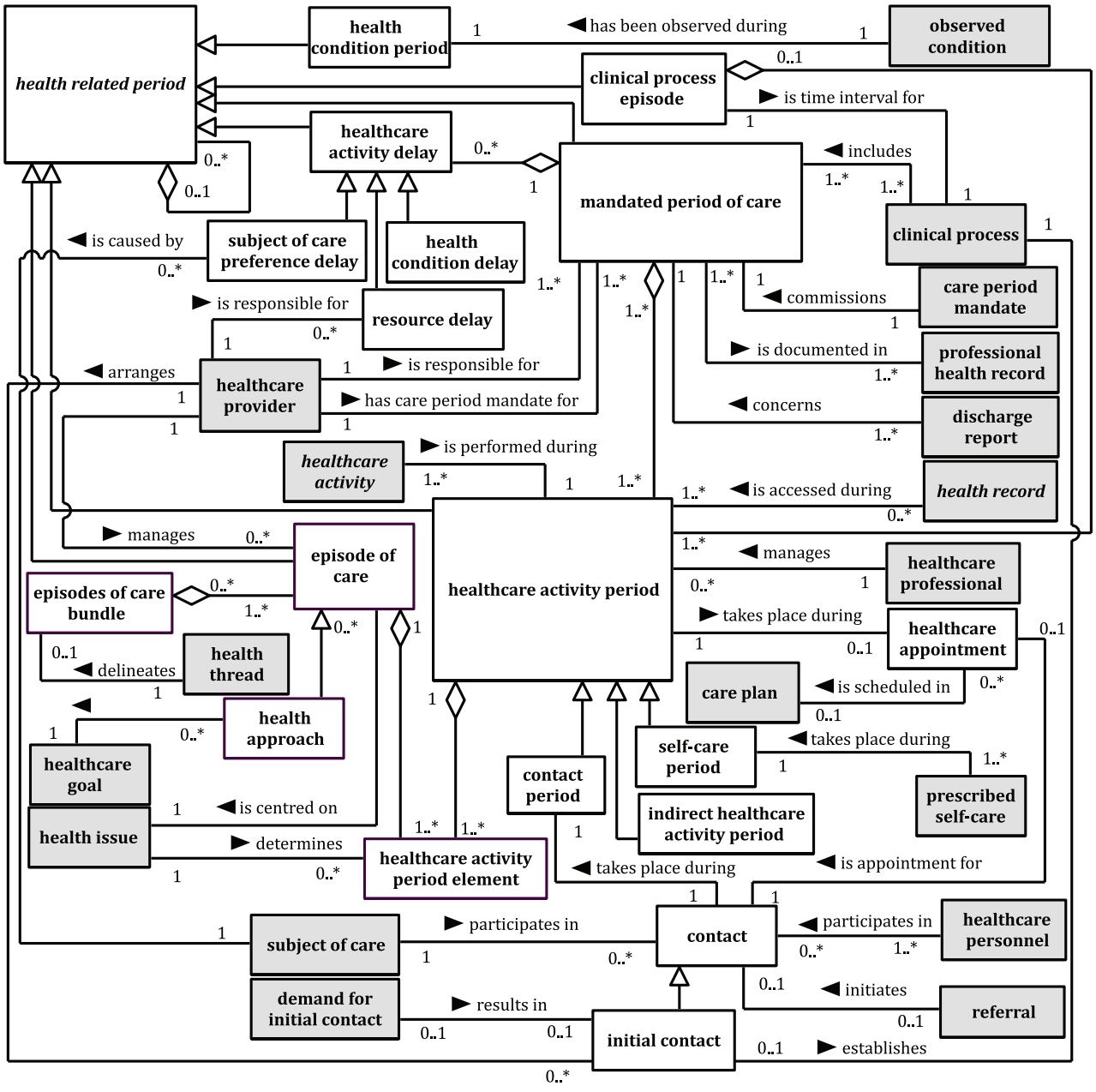

Figure 89 — Comprehensive UML diagram of concepts related to time

10.2 Health related period

Term: *health related period*

Definition: time interval related to the health of a *subject of care* and/or the provision of healthcare for that *subject of care*

NOTE 1 A *health related period* may be specialized in relation to a number of situations – a specific *clinical process*, *healthcare professional*, a specific department, a specific *health issue,* etc.

NOTE 2 A *health related period* is delineated by a 'start date and time' and an 'end date and time'. While the statement of the start date is generally easy by definition, the identification of the end date may be subject to specific rules that have to be agreed upon locally.

Table 80 lists the associations of this concept; a UML representation of the concept is shown in Figure 90.

Table 80 — Associations of *health related period*

Specialization of		**Generalization of**	
		mandated period of care	
		healthcare activity period	
		healthcare activity delay	
		episode of care	
		clinical process episode	
		health condition period	
Component of		**Aggregation of**	
0..1	health related period	0..*	health related period

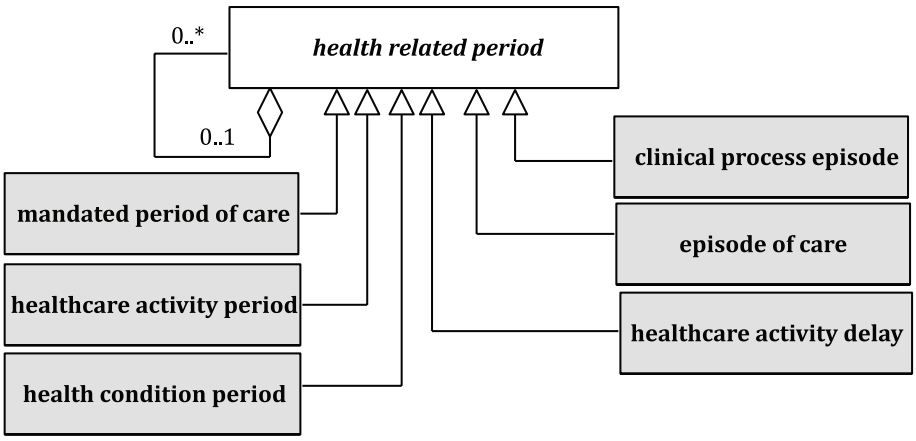

Figure 90 — Health related period (UML representation)

10.2.1 Mandated period of care

Term: *mandated period of care*

Synonym: commissioned period of care

Deprecated terms: period of care, period of healthcare

Definition: set of *healthcare activity periods* where a *healthcare provider* is mandated to perform the *healthcare activities* required to address specific *health needs*

NOTE 1 The *mandated period of care* is focused upon the framework of a care commitment of the provider as well as the mandate from the *subject of care,* which means that the roles and responsibilities of both the interacting parts are respected.

NOTE 2 Whenever the *healthcare provider* considered in a *mandated period of care* is a *healthcare organization*, this *mandated period of care* encompasses all *healthcare activity periods* with *healthcare professionals* who have a role in that *healthcare organization*.

NOTE 3 A *mandated period of care* may be part of another *mandated period of care*.

NOTE 4 In EN 13940–1:2007 period of care was the preferred term for this concept.

NOTE 5 The relevant information describing and produced during the *healthcare activities* performed as a part of a *mandated period of care* is recorded in one or more *professional health records.*

EXAMPLES A hospital stay, a series of radiotherapy sessions at an outpatient clinic.

Table 81 lists the associations of this concept; a UML representation of the concept is shown in Figure 91.

Table 81 — Associations of *mandated period of care*

Specialization of		**Generalization of**	
health related period			
Component of		**Aggregation of**	
		1..*	healthcare activity period
		0..*	healthcare activity delay

Association from		**Association name**	**Association to**	
1	care period mandate	commissions	1	mandated period of care
1..*	mandated period of care	is documented in	1..*	professional health record
1..*	clinical process	includes	1..*	mandated period of care
1	healthcare provider	has care period mandate for	1..*	mandated period of care
1	healthcare provider	is responsible for	1..*	mandated period of care
1..*	discharge report	concerns	1	mandated period of care

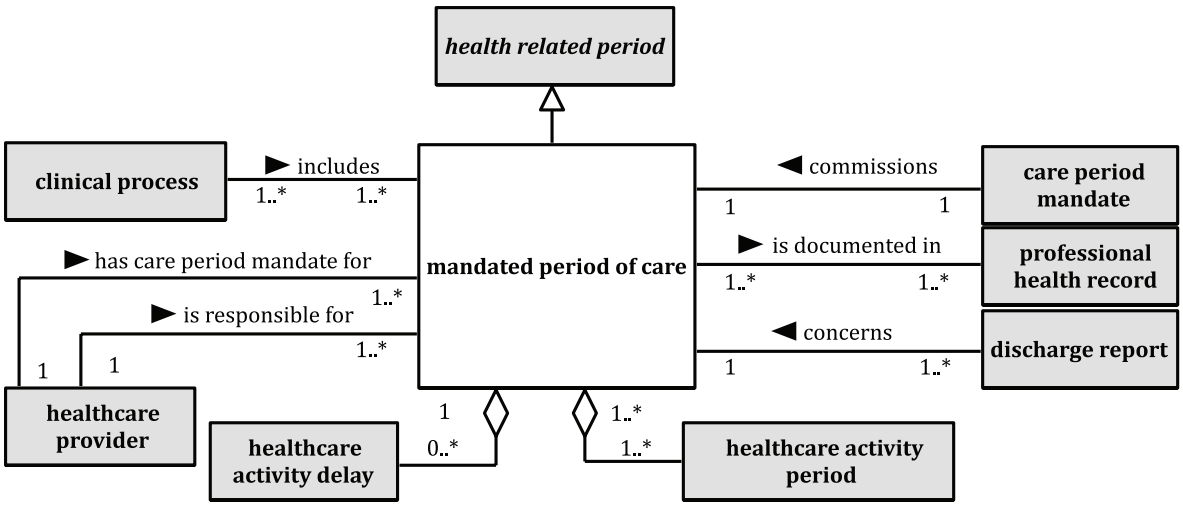

Figure 91 — Mandated period of care (UML representation)

10.2.2 Healthcare activity period

Term: *healthcare activity period*

Deprecated term: contact

Definition: time interval during which *healthcare activities* are performed for a *subject of care*

NOTE In EN 13940–1:2007 contact was the preferred term for this concept.

Table 82 lists the associations of this concept; a UML representation of the concept is shown in Figure 92.

Table 82 — Associations of *healthcare activity period*

Specialization of		**Generalization of**	
health related period		contact period	
		indirect healthcare activity period	
		self-care period	
Component of		**Aggregation of**	
1..*	mandated period of care	1..*	healthcare activity period element
0..1	clinical process episode		

Association from		**Association name**	**Association to**	
1	healthcare activity period	takes place during	0..1	healthcare appointment
1	healthcare professional	manages	0..*	healthcare activity period
1..*	healthcare activity	is performed during	1	healthcare activity period
0..*	health record	is accessed during	1..*	healthcare activity period

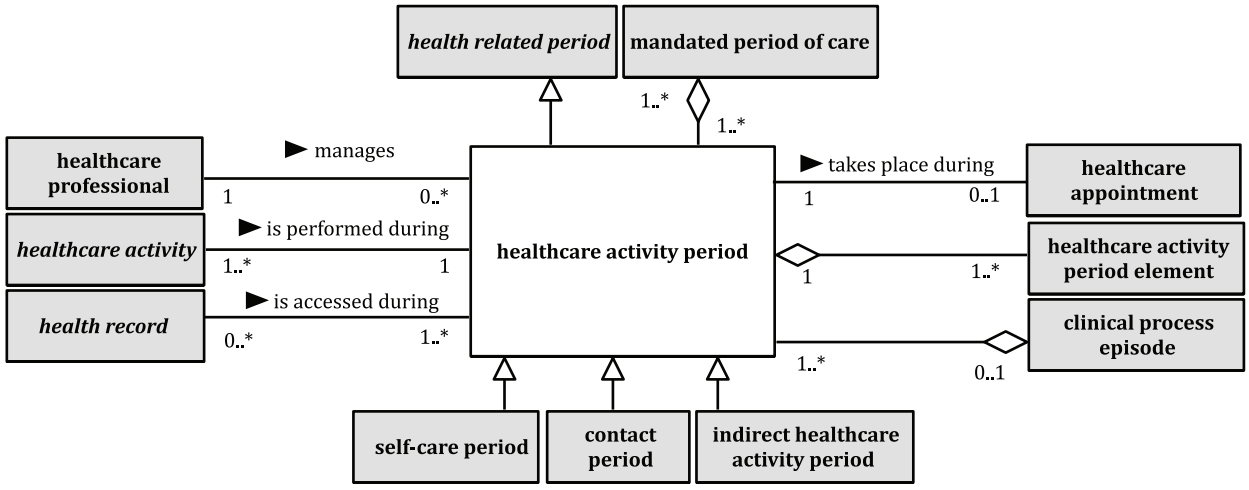

Figure 92 — Healthcare activity period (UML representation)

10.2.2.1 Contact period

Term: *contact period*

Synonym: encounter

Definition: *healthcare activity period* during which a *contact* occurs

NOTE 1 Since during a *contact*, more than one *health issue* may be addressed, it may relate to more than one *healthcare process* and more than one *episode of care*.

NOTE 2 In EN 13940–1:2007 the concept encounter was defined as '*contact* in the course of which *healthcare activities* are delivered to a *subject of care* in her or his presence'.

EXAMPLES Face to face contact with a GP, telephone contact, telemedicine contact.

Table 83 lists the associations of this concept; a UML representation of the concept is shown in Figure 93.

Table 83 — Associations of *contact period*

Specialization of		**Generalization of**		
healthcare activity period				
Association from		**Association name**	**Association to**	
1	contact	takes place during	1	contact period

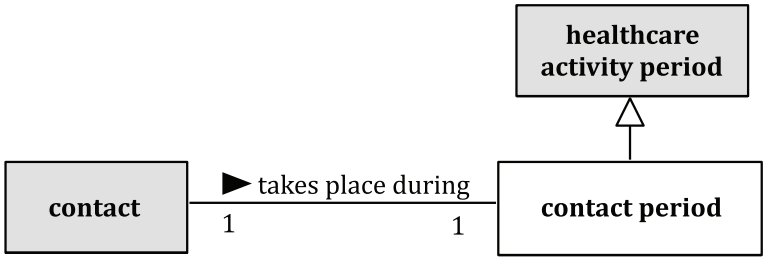

Figure 93 — Contact period (UML representation)

10.2.2.1.1 Contact

Term: *contact*

Synonym: healthcare contact

Definition: interaction between a *subject of care* and one or more *healthcare personnel*

Table 84 lists the associations of this concept; a UML representation of the concept is shown in Figure 94.

Table 84 — Associations of *healthcare contact*

Specialization of		**Generalization of**		
		initial contact		
Association from		**Association name**	**Association to**	
1	contact	takes place during	1	contact period
1	subject of care	participates in	0..*	contact
1..*	healthcare personnel	participates in	0..*	contact
0..1	referral	initiates	0..1	contact
0..1	healthcare appointment	is appointment for	1	contact

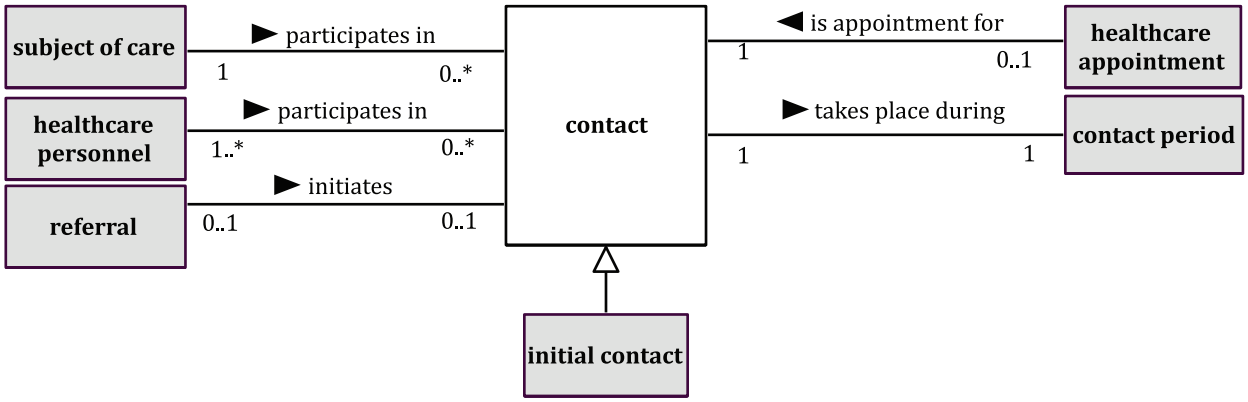

Figure 94 — Contact (UML representation)

10.2.2.1.2 Initial contact

Term: *initial contact*

Definition: *contact* during which a *clinical process* is initiated

Table 85 lists the associations of this concept; a UML representation of the concept is shown in Figure 95.

Table 85 — Associations of *initial contact*

Specialization of		**Generalization of**		
contact				
Association from		**Association name**	**Association to**	
0..1	initial contact	establishes	1	clinical process
0..1	demand for initial contact	results in	0..1	initial contact
1	healthcare provider	arranges	0..*	initial contact

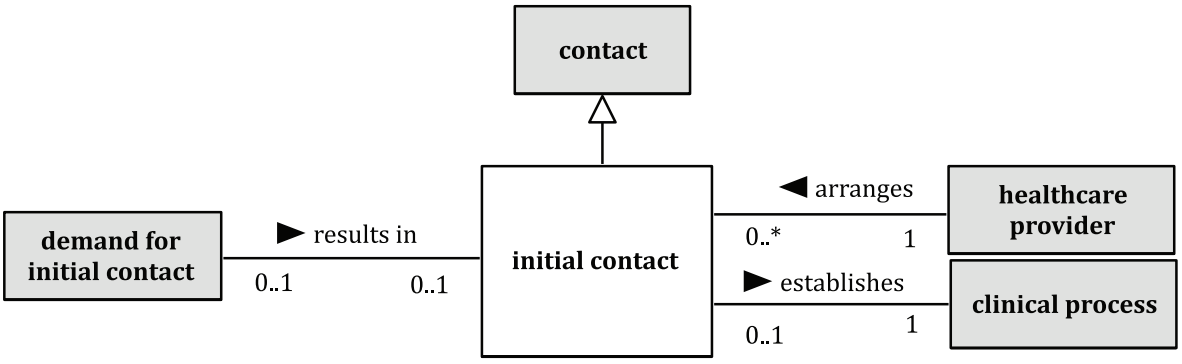

Figure 95 — Initial contact (UML representation)

10.2.2.2 Indirect healthcare activity period

Term: *indirect healthcare activity period*

Deprecated term: record contact

Definition: *healthcare activity period* without the involvement of the *subject of care*

NOTE 1 In EN 13940–1:2007 the concept record contact was defined as '*contact* restricted to the access to the *professional health record* of a *subject of care* by a *healthcare professional* for its management, out of the presence of that *subject of care*'.

EXAMPLE 1 The period where *healthcare activities* are performed without the presence of the *subject of care* in order to decide whether a *referral* or a *demand for initial contact* should be accepted or not

EXAMPLE 2 Time spent working on laboratory or tissue specimens taken from a subject of care

EXAMPLE 3 Period taken for the planning of care

Table 86 lists the associations of this concept; a UML representation of the concept is shown in Figure 96.

Table 86 — Associations of *indirect healthcare activity period*

Specialization of	**Generalization of**
healthcare activity period	

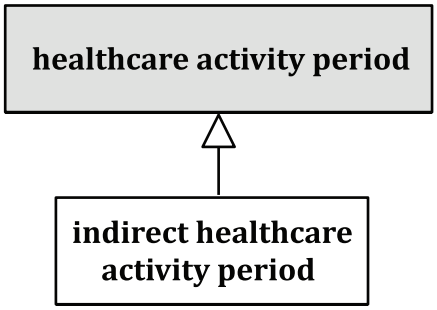

Figure 96 — Indirect healthcare activity period (UML representation)

10.2.2.3 Self-care period

Term: *self-care period*

Definition: *healthcare activity period* where *prescribed self-care is* performed

Table 87 lists the associations of this concept; a UML representation of the concept is shown in Figure 97.

Table 87 — Associations of *self-care period*

Specialization of		**Generalization of**		
healthcare activity period				
Association from		**Association name**	**Association to**	
1..*	prescribed self-care	takes place during	1	self-care period

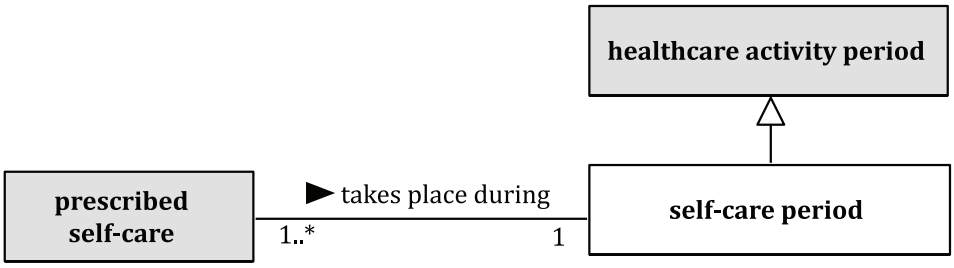

Figure 97 — Self-care period (UML representation)

10.2.2.4 Healthcare activity period element

Term: *healthcare activity period element*

Deprecated term: contact element

Definition: part of a *healthcare activity period* during which one *health issue* is specifically addressed

NOTE 1 Several *healthcare activity period elements* may take place during the course of a *healthcare activity period*.

NOTE 2 A *healthcare activity period element* is part of only one *healthcare activity period* and of *only one episode of care*.

NOTE 3 In EN 13940–1:2007 contact element was the preferred term for this concept.

EXAMPLE The part of a consultation that addresses the follow-up of a hypertension treatment, but not the other part of the same consultation that is devoted to the treatment of diabetes mellitus.

Table 88 lists the associations of this concept; a UML representation of the concept is shown in Figure 98.

Table 88 — Associations of *healthcare activity period element*

Component of		**Aggregation of**	
1	healthcare activity period		
1	episode of care		

Association from		**Association name**	**Association to**	
1	health issue	determines	0..*	healthcare activity period element

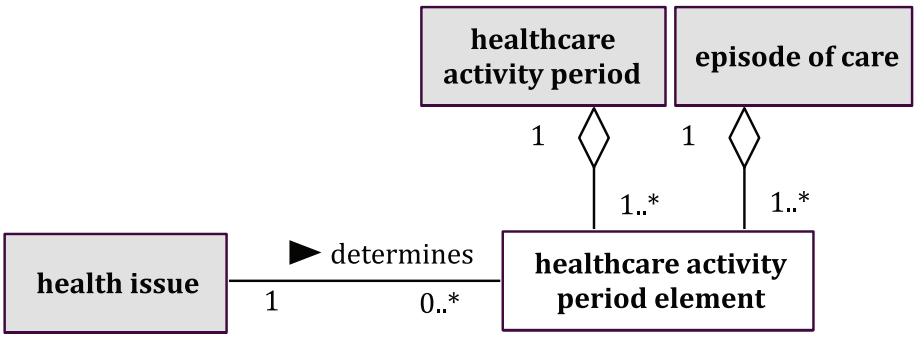

Figure 98 — Healthcare activity period element (UML representation)

10.2.2.5 Healthcare appointment

Term: *healthcare appointment*

Definition: appointment for a *contact*

Table 89 lists the associations of this concept; a UML representation of the concept is shown in Figure 99.

Table 89 — Associations of *healthcare appointment*

Association from		Association name	Association to	
0..*	healthcare appointment	is scheduled in	0..1	care plan
1	healthcare activity period	takes place during	0..1	healthcare appointment
0..1	healthcare appointment	is appointment for	1	contact

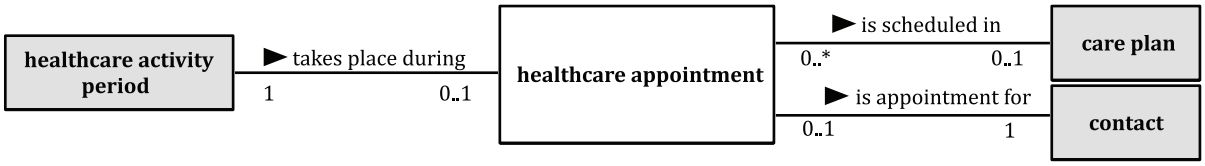

Figure 99 — Healthcare appointment (UML representation)

10.2.3 Healthcare activity delay

Term: *healthcare activity delay*

Definition: *health related period* during which a *healthcare activity* is planned but not started

Table 90 lists the associations of this concept; a UML representation of the concept is shown in Figure 100.

Table 90 — Associations of *healthcare activity delay*

Specialization of	Generalization of
health related period	health condition delay
	resource delay
	subject of care preference delay

Component of		Aggregation of	
1	mandated period of care		

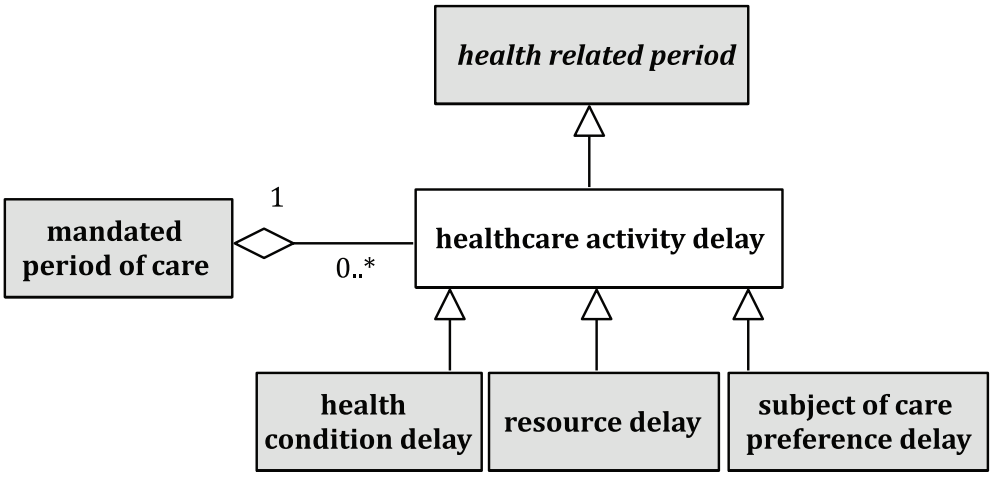

Figure 100 — Healthcare activity delay (UML representation)

10.2.3.1 Health condition delay

Term: *health condition delay*

Definition: *healthcare activity delay* caused by a *health condition*

EXAMPLE 1 surgery delayed because the *subject of care* is pregnant

EXAMPLE 2 cervical examination delayed during menstruation

Table 91 lists the associations of this concept; a UML representation of the concept is shown in Figure 101.

Table 91 — Associations of *health condition delay*

Specialization of	Generalization of
healthcare activity delay	

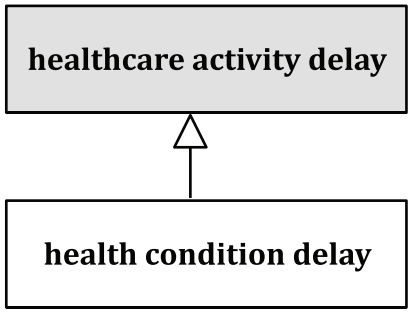

Figure 101 — Health condition delay (UML representation)

10.2.3.2 Resource delay

Term: *resource delay*

Definition: *healthcare activity delay* caused by resource constraints where there is no *health condition delay*

EXAMPLE 1 *healthcare activity* scheduled later than clinically indicated to allow resources to be deployed on other *subjects of care* (a waiting list)

EXAMPLE 2 *healthcare activity* postponed while necessary financial resources are identified

Table 92 lists the associations of this concept; a UML representation of the concept is shown in Figure 102.

Table 92 — Associations of *resource delay*

Specialization of		**Generalization of**		
healthcare activity delay				
Association from		**Association name**	**Association to**	
1	healthcare provider	is responsible for	0..*	resource delay

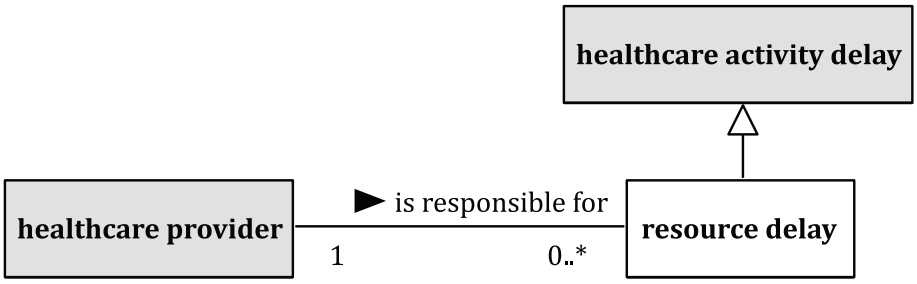

Figure 102 — Resource delay (UML representation)

10.2.3.3 Subject of care preference delay

Term: *subject of care preference delay*

Definition: *healthcare activity delay* by the preference of the *subject of care*, where there is neither a *health condition delay* nor a *resource delay*

EXAMPLE 1 surgery delayed to enable the *subject of care* to undertake seasonal work

EXAMPLE 2 investigation delayed to support the *subject of care's* scheduling choice

Table 93 lists the associations of this concept; a UML representation of the concept is shown in Figure 103.

Table 93 — Associations of *subject of care preference delay*

Specialization of		**Generalization of**		
healthcare activity delay				
Association from		**Association name**	**Association to**	
0..*	subject of care preference delay	is caused by	1	subject of care

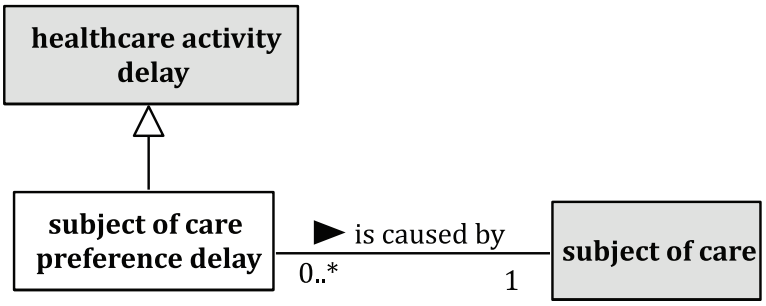

Figure 103 — Subject of care preference delay (UML representation)

10.2.4 Clinical process episode

Term: *clinical process episode*

Definition: *health related period* that includes all *healthcare activity periods* in one *clinical process*

Table 94 lists the associations of this concept; a UML representation of the concept is shown in Figure 104.

Table 94 — Associations of *clinical process episode*

Specialization of			**Generalization of**		
health related period					
Component of			**Aggregation of**		
			1..*	healthcare activity period	
Association from		**Association name**	**Association to**		
1	clinical process episode	is time interval for	1	clinical process	

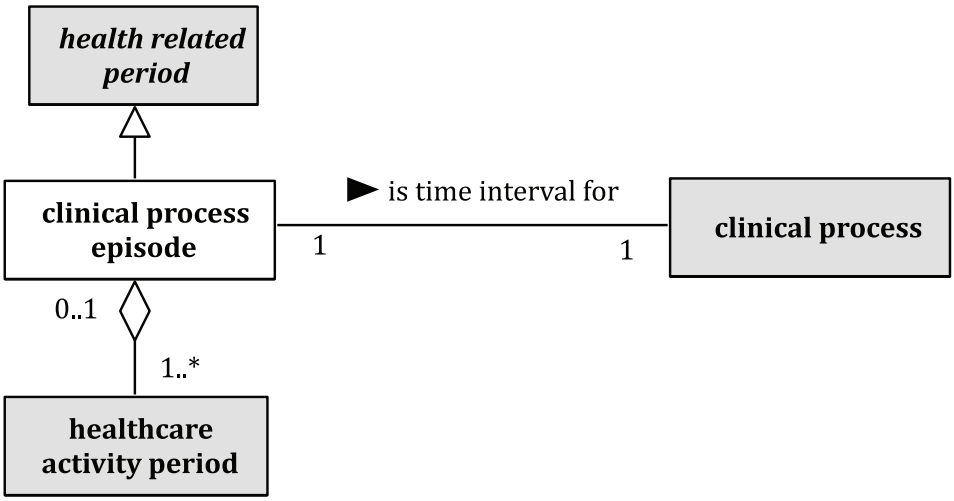

Figure 104 — Clinical process episode (UML representation)

10.2.5 Health condition period

Term: *health condition period*

Definition: *health related period* during which a *health condition* has been observed

NOTE 1 Observation of a *health condition* may lead to an *episode of care*

NOTE 2 *Health condition period* refers only to the observation of the *health condition*, for example, the time interval during which a *subject of care* has observed a bleeding. The concept *episode of care* is referring to the *healthcare activities*.

Table 95 lists the associations of this concept; a UML representation of the concept is shown in Figure 105.

Table 95 — Associations of *health condition period*

Specialization of		**Generalization of**		
health related period				
Association from		**Association name**	**Association to**	
1	observed condition	has been observed during	1	health condition period

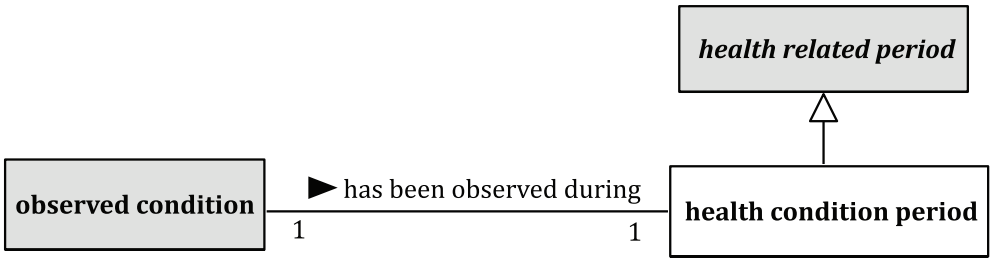

Figure 105 — Health condition period (UML representation)

10.2.6 Episode of care

Term: *episode of care*

Synonyms: episode of healthcare, health issue related episode

Definition: *health related period* during which *healthcare activities* are performed to address one *health issue* as identified by one *healthcare professional*

NOTE 1 An *episode of care* encompasses all *healthcare activity period elements* related to the same *health issue*.

NOTE 2 An *episode of care* starts with the very first *contact* with a *healthcare provider* for a *health issue* and it ends after the completion of all *healthcare activities* related to the last *contact* with that *healthcare provider* for the same *health issue*.

NOTE 3 For practical reasons (e.g. the need to state start and end dates) and also because it relates specifically to a *health issue* defined by a given *healthcare professional*, an *episode of care* does not necessarily coincide with an 'episode of illness' (or of disease, or of any other kind of *health issue*).

NOTE 4 During a *mandated period of care* several *health issues* may be handled and as such be linked to several *episodes of care*. These *episodes of care* are said to be 'concurrent'.

EXAMPLES An episode of urinary tract infection, an episode of cholecystectomy.

Table 96 lists the associations of this concept; a UML representation of the concept is shown in Figure 106.

Table 96 — Associations of *episode of care*

Specialization of		**Generalization of**	
health related period		health approach	
Component of		**Aggregation of**	
0..*	episodes of care bundle	1..*	healthcare activity period element

Association from		**Association name**	**Association to**	
0..*	episode of care	is centred on	1	health issue
1	healthcare provider	manages	0..*	episode of care

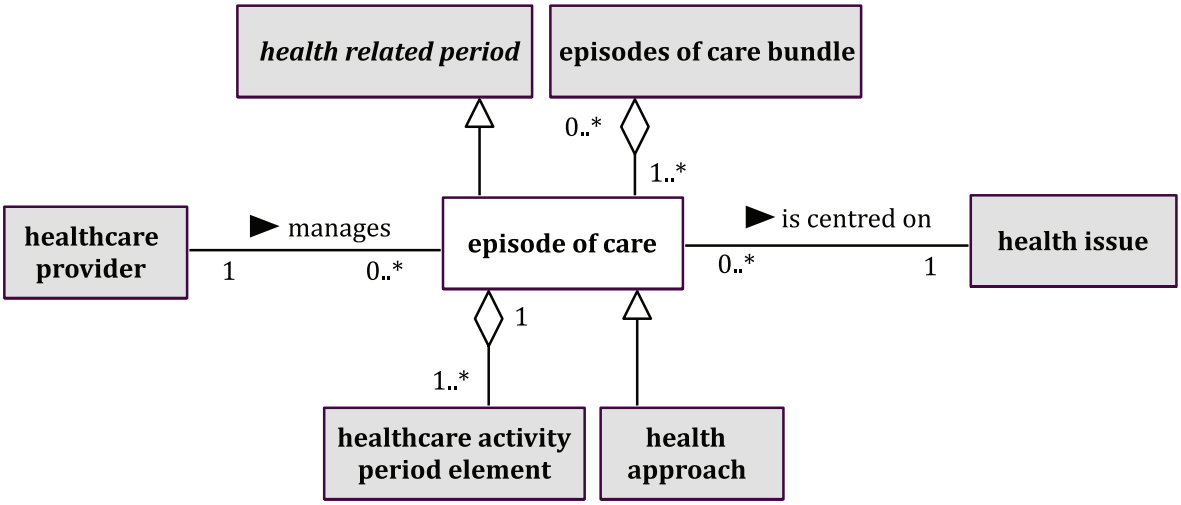

Figure 106 — Episode of care (UML representation)

10.2.6.1 Health approach

Term: *health approach*

Synonyms: healthcare approach, goal-addressing episode of care

Definition: *episode of care* during which the *healthcare activities* performed address one specific *healthcare goal*

Table 97 lists the associations of this concept; a UML representation of the concept is shown in Figure 107.

Table 97 — Associations of *health approach*

Specialization of		**Generalization of**	
episode of care			

Association from		**Association name**	**Association to**	
0..*	health approach	addresses	1	healthcare goal

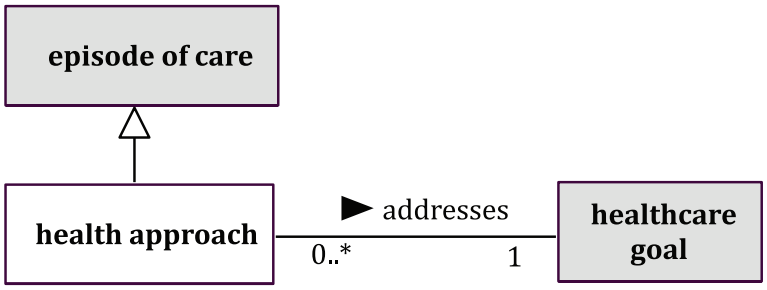

Figure 107 — Health approach (UML representation)

10.2.6.2 Episodes of care bundle

Term: *episodes of care bundle*

Synonyms: episodes of healthcare bundle, cumulative episode of care

Definition: group of *episodes of care* delineated by a *health thread*

NOTE 1 An *episodes of care bundle* starts with the very first *contact* with a *healthcare provider* for a *health issue* considered in a *health thread* and ends after the completion of all *healthcare activities* related to the last *contact* with any *healthcare provider* for a *health issue* encompassed in the same *health thread*.

NOTE 2 As different *health threads* may be considered that reconcile the perspectives of different *healthcare actors* (e.g. a care team manager, or a health authority) or sets of *healthcare actors*, there may exist different *health threads* according to the specific perspectives of those sets of *healthcare actors* that justify building up such *health threads*. As a consequence there may exist as many *episodes of care bundles* as there are such *health threads*.

NOTE 3 From the *electronic health record* point of view, an *episodes of care bundle* shows the overall *healthcare activity period elements* related to those *health issues* that are linked by the same *health thread*.

NOTE 4 In EN 13940–1:2007 cumulative episode of care was the preferred term for this concept.

EXAMPLES A cumulative episode of diabetes mellitus, a cumulative episode of breast cancer.

Table 98 lists the associations of this concept; a UML representation of the concept is shown in Figure 108.

Table 98 — Associations of *episodes of care bundle*

Component of		**Aggregation of**	
		1..*	episode of care

Association from		**Association name**	**Association to**	
1	health thread	delineates	0..1	episodes of care bundle

Figure 108 — Episodes of care bundle (UML representation)

11 Concepts related to responsibilities

11.1 General

A model showing the associations between the concepts related to responsibility in continuity of care and the other concepts defined in this International Standard is shown in Figure 109. For further detail about the diagram notation, please refer to 0.7 in the Introduction.

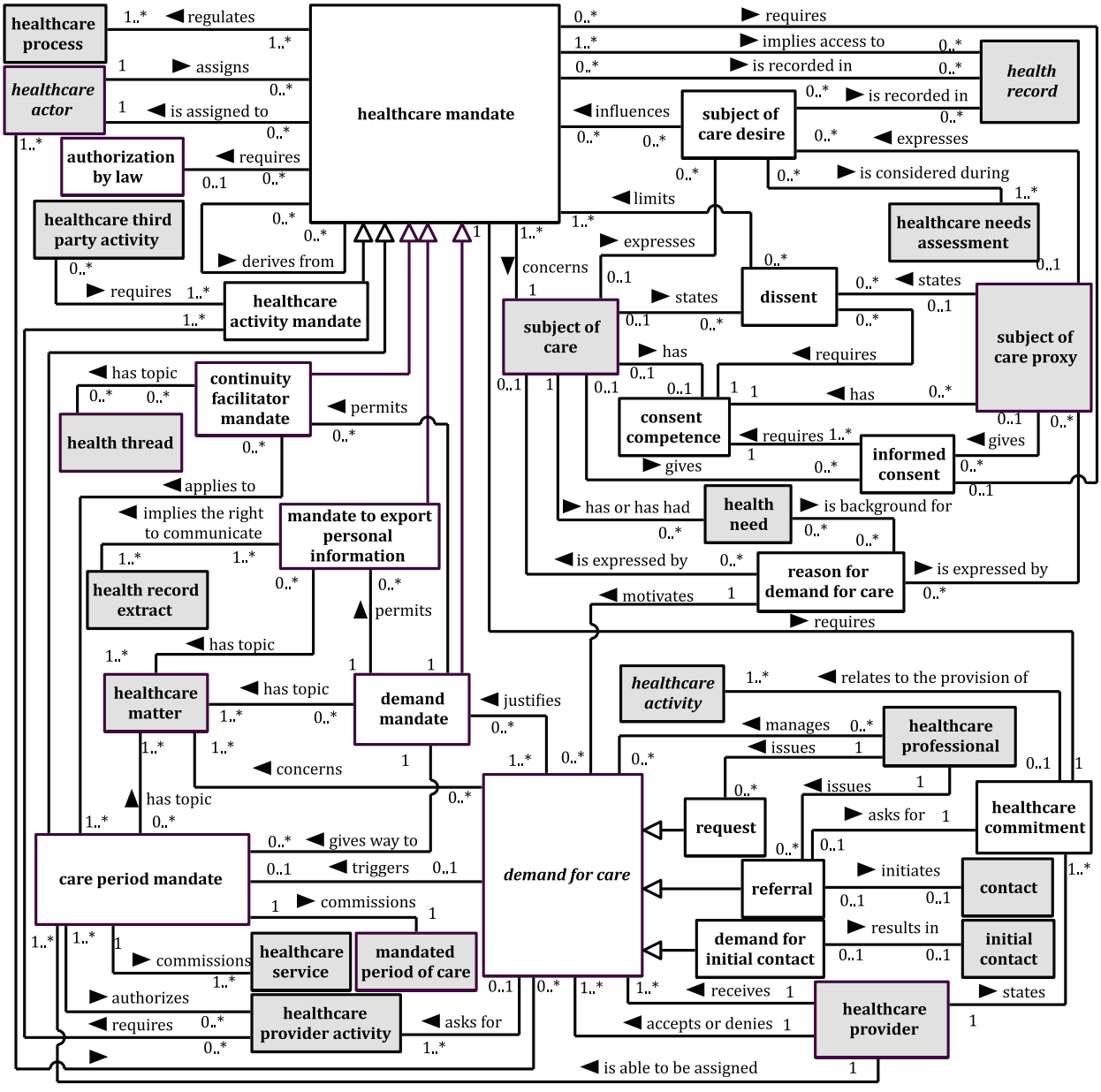

Figure 109 — Comprehensive UML-diagram of the concepts related to responsibilities

11.2 Healthcare mandate

Term: *healthcare mandate*

Synonym: healthcare commission

Definition: 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*

NOTE 1 A *healthcare mandate* can be explicit or implicit

NOTE 2 Relevant information related to *healthcare mandates* (including *demands for care*, *informed consents*, *dissents*, *healthcare commitments,* etc.), is recorded in *health records* where the information is made available for concerned *healthcare actors* as *health concerns.*

NOTE 3 Typically a *healthcare mandate* is assigned by one *healthcare actor* to another.

NOTE 4 In EN 13940–1:2007 health mandate was the preferred term for this concept.

Table 99 lists the associations of this concept; a UML representation of the concept is shown in Figure 110.

Table 99 — Associations of *healthcare mandate*

Specialization of	**Generalization of**
	demand mandate
	care period mandate
	continuity facilitator mandate
	healthcare activity mandate
	mandate to export personal information

Association from		**Association name**	**Association to**	
1..*	healthcare mandate	concerns	1	subject of care
1..*	healthcare mandate	regulates	1..*	healthcare processes
0..*	healthcare mandate	requires	0..1	informed consent
0..*	healthcare mandate	requires	0..1	authorization by law
0..*	healthcare mandate	is recorded in	0..*	health record
1..*	healthcare mandate	implies access to	0..*	health record
1	healthcare mandate	requires	1	healthcare commitment
0..*	healthcare mandate	derives from	0..*	healthcare mandate
0..*	healthcare mandate	is assigned to	1	healthcare actor
1	healthcare actor	assigns	0..*	healthcare mandate
0..*	dissent	limits	1..*	healthcare mandate
0..*	subject of care desire	influences	0..*	healthcare mandate

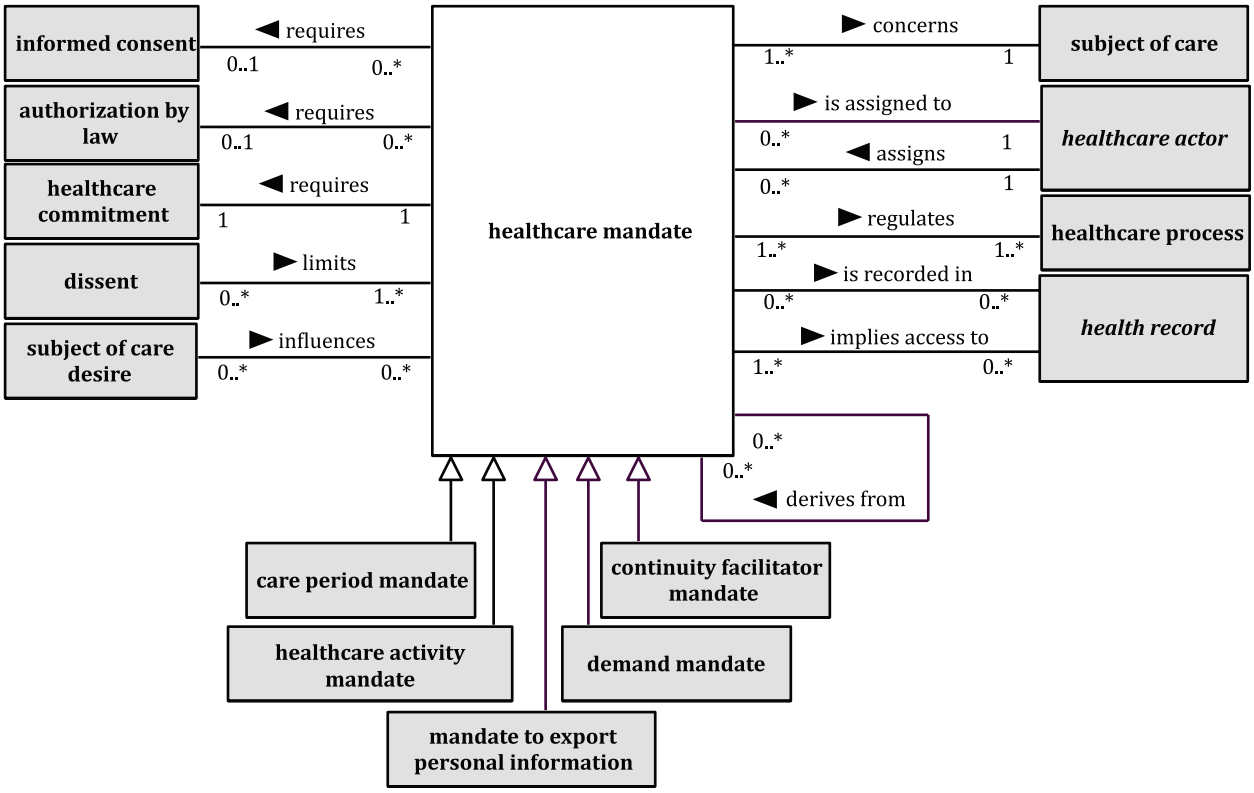

Figure 110 — Healthcare mandate (UML representation)

11.2.1 Demand mandate

Term: *demand mandate*

Synonym: demand commission

Definition: *healthcare mandate* implying the right and obligation to demand *healthcare activities*

NOTE 1 A *demand for care* is usually made by a *subject of care* him/herself, but there are circumstances where the *subject of care* is not in the position of making a *demand for care*. In that case, it has to be made on their behalf by another person.

NOTE 2 Within certain jurisdictions a generic *demand mandate* may be explicitly or implicitly assigned to certain categories of citizens on the basis of their specific roles. It may also be directly or indirectly made necessary by law that such generic mandates are explicitly established.

EXAMPLES

A *subject of care* requesting *healthcare* from a GP.

Care for a child requested by a parent.

A passer-by may in some jurisdictions be obliged to seek care for any endangered person, for example unconscious after a road accident.

Table 100 lists the associations of this concept; a UML representation of the concept is shown in Figure 111.

Table 100 — Associations of *demand mandate*

Specialization of	**Generalization of**
healthcare mandate	

Table 100 *(continued)*

Association from		Association name	Association to	
1..*	demand for care	justifies	0..*	demand mandate
0..*	demand mandate	has topic	1..*	healthcare matter
1	demand mandate	gives way to	0..*	care period mandate
1	demand mandate	permits	0..*	continuity facilitator mandate
1	demand mandate	permits	0..*	mandate to export personal information

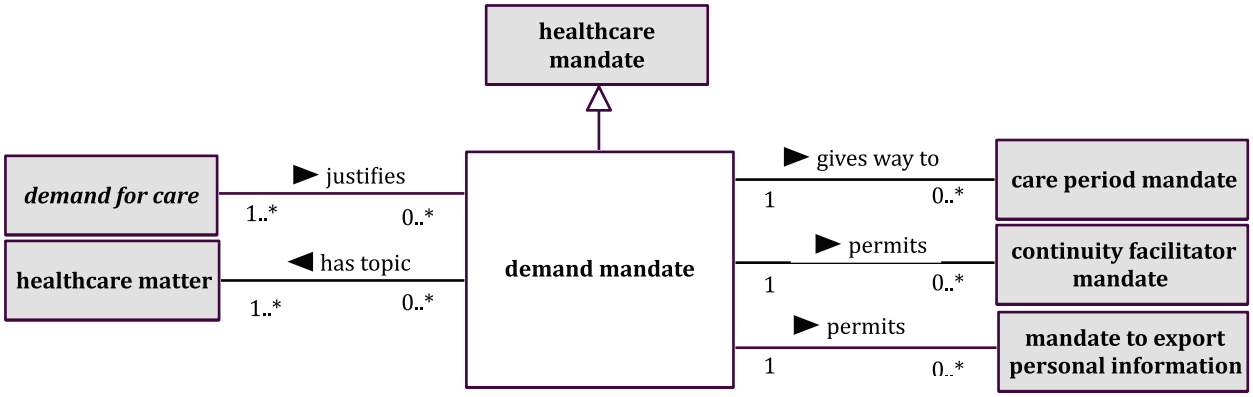

Figure 111 — Demand mandate (UML representation)

11.2.2 Care period mandate

Term: *care period mandate*

Synonym: healthcare period mandate

Deprecated term: care mandate

Definition: *healthcare mandate* commissioning a *mandated period of care*

NOTE 1 A *care period mandate* may be an agreement between the *subject of care* and a *healthcare provider* to provide specified *healthcare services in a mandated period of care*.

NOTE 2 In EN 13940–1:2007 care mandate was the preferred term for this concept.

Table 101 lists the associations of this concept; a UML representation of the concept is shown in Figure 112.

Table 101 — Associations of *care period mandate*

Specialization of	Generalization of
healthcare mandate	

Association from		Association name	Association to	
0..*	care period mandate	has topic	1..*	healthcare matter
1..*	care period mandate	authorizes	0..*	healthcare provider activity
1	demand mandate	gives way to	0..*	care period mandate
0..1	demand for care	triggers	0..1	care period mandate
1	care period mandate	commissions	1..*	healthcare services
1	care period mandate	commissions	1	mandated period of care

Table 101 *(continued)*

0..*	continuity facilitator mandate	applies to	1..*	care period mandate
1	healthcare provider	is able to be assigned	1..*	care period mandate

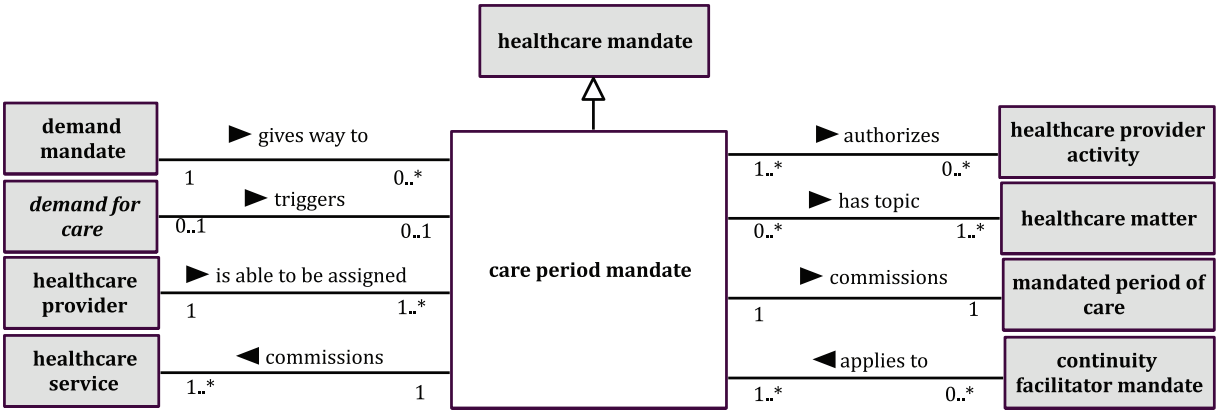

Figure 112 — Care period mandate (UML representation)

11.2.3 Healthcare activity mandate

Term: *healthcare activity mandate*

Synonym: healthcare activity commission

Definition: *healthcare mandate* assigning the right and obligation to perform specific *healthcare activities*

Table 102 lists the associations of this concept; a UML representation of the concept is shown in Figure 113.

Table 102 — Associations of *healthcare activity mandate*

Specialization of	**Generalization of**
healthcare mandate	

Association from		**Association name**	**Association to**	
0..*	healthcare provider activity	requires	1..*	Healthcare activity mandate
0..*	healthcare third party activity	requires	1..*	Healthcare activity mandate

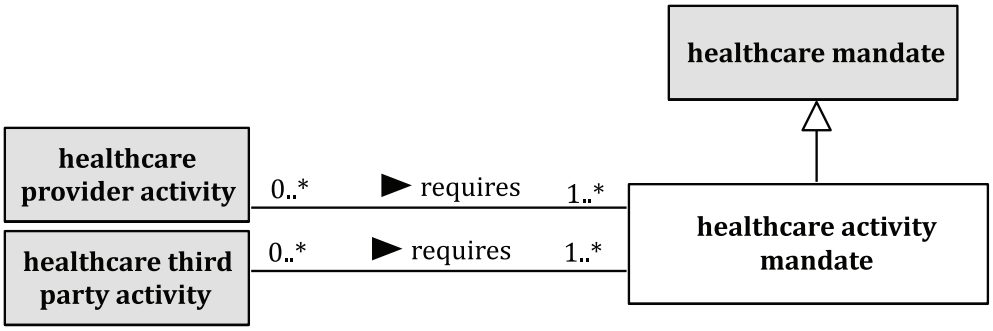

Figure 113 — Healthcare activity mandate (UML representation)

11.2.4 Continuity facilitator mandate

Term: *continuity facilitator mandate*

Synonym: continuity facilitator commission

Definition: *healthcare mandate* assigning the right and obligation to monitor and coordinate the delivery of care described in those *care period mandates* related to *healthcare matters* linked by specific *health threads*

NOTE 1 Beyond solely assuming the function described above, a continuity facilitator may also assume the function of a lead and/or coordinator of *healthcare activities* delivered to the *subject of care*

NOTE 2 A continuity facilitation can be fulfilled only if the involved healthcare actors have the information needed to perform their tasks in healthcare activities

NOTE 3 For continuity of care the *continuity facilitator mandates* for *complete clinical processes* are of special importance from the *subject of care's* perspective.

EXAMPLE A mandate assigned to a coordinating nurse, to a lead GP, key-worker, etc. to coordinate care

Table 103 lists the associations of this concept; a UML representation of the concept is shown in Figure 114.

Table 103 — Associations of *continuity facilitator mandate*

Specialization of	**Generalization of**
healthcare mandate	

Association from		**Association name**	**Association to**	
0..*	continuity facilitator mandate	has topic	0..*	health thread
1	demand mandate	permits	0..*	continuity facilitator mandate
0..*	continuity facilitator mandate	applies to	1..*	care period mandate

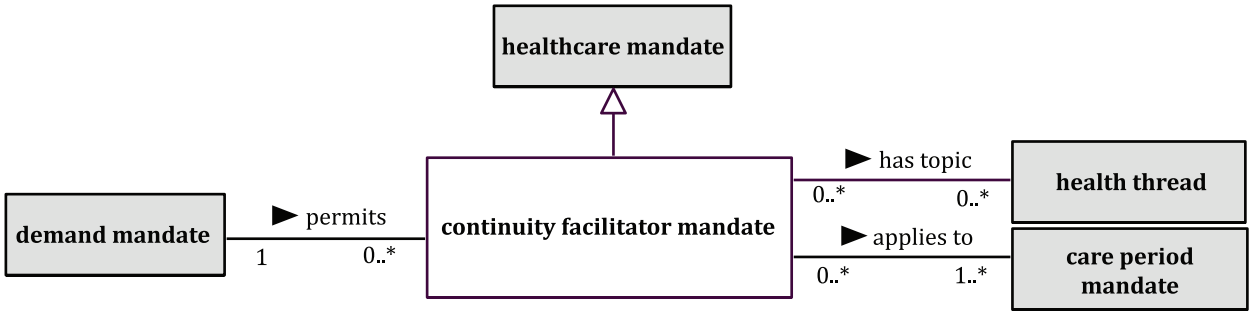

Figure 114 — Continuity facilitator mandate (UML representation)

11.2.5 Mandate to export personal information

Term: *mandate to export personal information*

Synonym: commission to export personal information

Definition: *healthcare mandate* implying the right to communicate *health record extracts*

EXAMPLE 1 A *request* to a doctor to write a letter to a medical specialist stating the reasons of a *referral*

EXAMPLE 2 A *request* to a GP by a *subject of care* for the transfer of his or her *health record* to another GP, when that *subject of care* moves to another part of the country.

Table 104 lists the associations of this concept; a UML representation of the concept is shown in Figure 115.

Table 104 — Associations of *mandate to export personal information*

Specialization of	**Generalization of**
healthcare mandate	

Association from		**Association name**	**Association to**	
0..*	mandate to export personal information	has topic	1..*	healthcare matter
1..*	mandate to export personal information	implies the right to communicate	1..*	health record extracts
1	demand mandate	permits	0..*	mandate to export personal information

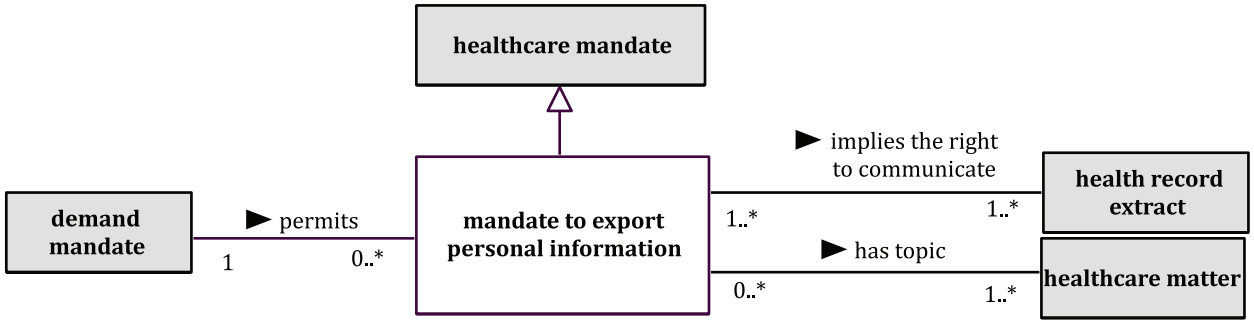

Figure 115 — Mandate to export personal information (UML representation)

11.2.6 Informed consent

Term: *informed consent*

Definition: permission to perform *healthcare activities*, voluntarily given by a *subject of care* having *consent competence,* or by a *subject of care proxy*, after having been informed about the purpose and the possible results of the *healthcare activities*

NOTE A *healthcare mandate* requires either *informed consent* or *authorization by law.*

Table 105 lists the associations of this concept; a UML representation of the concept is shown in Figure 116.

Table 105 — Associations of *informed consent*

Association from		**Association name**	**Association to**	
1..*	informed consent	requires	1	consent competence
0..1	subject of care	gives	0..*	informed consent
0..1	subject of care proxy	gives	0..*	informed consent
0..*	healthcare mandate	requires	0..1	informed consent

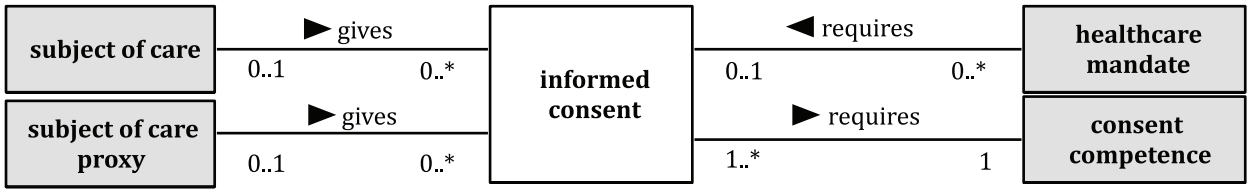

Figure 116 — Informed consent (UML representation)

11.2.7 Dissent

Term: *dissent*

Definition: refusal to permit specific *healthcare activities* to be performed

Table 106 lists the associations of this concept; a UML representation of the concept is shown in Figure 117.

Table 106 — Associations of *dissent*

Association from		Association name	Association to	
0..*	dissent	requires	1	consent competence
0..*	dissent	limits	1..*	healthcare mandate
0..1	subject of care	states	0..*	dissent
0..1	subject of care proxy	states	0..*	dissent

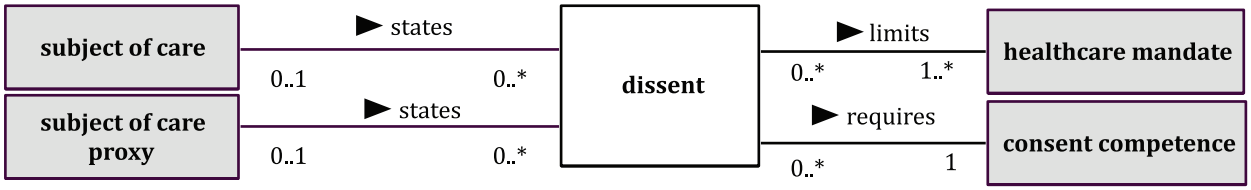

Figure 117 — Dissent (UML representation)

11.2.8 Consent competence

Term: *consent competence*

Definition: capability of the *subject of care* and/or the *subject of care proxy* to give *informed consent* or *dissent*

Table 107 lists the associations of this concept; a UML representation of the concept is shown in Figure 118.

Table 107 — Associations of *consent competence*

Association from		Association name	Association to	
1..*	informed consent	requires	1	consent competence
0..*	dissent	requires	1	consent competence
0..*	subject of care proxy	has	1	consent competence
0..1	subject of care	has	0..1	consent competence

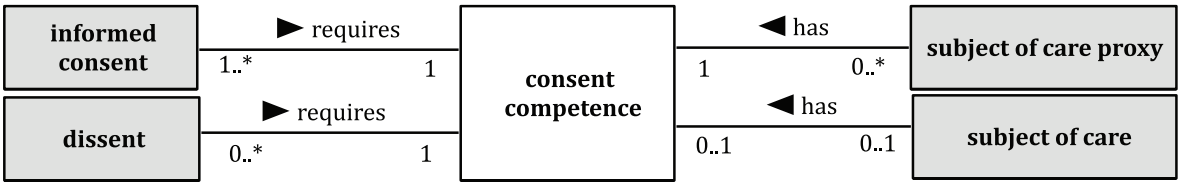

Figure 118 — Consent competence (UML representation)

11.2.9 Authorization by law

Term: *authorization by law*

Definition: provision in legislation that in certain circumstances may overrule the need for *informed consent*

NOTE A *healthcare mandate* requires either *informed consent* or *authorization by law*.

Table 108 lists the associations of this concept; a UML representation of the concept is shown in Figure 119.

Table 108 — Associations of *authorization by law*

Association from		Association name	Association to	
0..*	healthcare mandate	requires	0..1	authorization by law

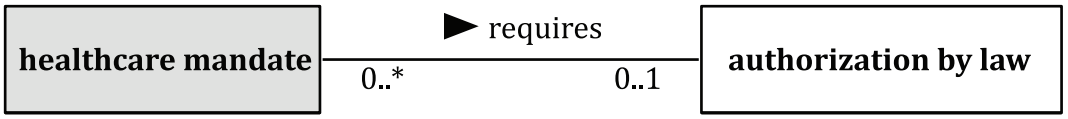

Figure 119 — Authorization by law (UML representation)

11.2.10 Healthcare commitment

Term: *healthcare commitment*

Synonym: care commitment

Definition: acceptance of a *healthcare mandate* by the *healthcare actor* to whom it is assigned

NOTE 1 The *healthcare commitment* is the promise by the *healthcare actor* to perform *healthcare activities*. This also means that the *healthcare provider* accepts and confirms the pending *healthcare mandate* issued through the proposed care plan. It is only once the *healthcare commitment* has been stated that an effective *healthcare mandate* exists and will be the legal framework for all *healthcare activities* of the subsequent *healthcare process*.

NOTE 2 Implicitly, a *healthcare commitment* results from a dialogue with the *subject of care* or someone on behalf of the *subject of care* within a *healthcare needs assessment*

Table 109 lists the associations of this concept; a UML representation of the concept is shown in Figure 120.

Table 109 — Associations of *authorization by law*

Association from		Association name	Association to	
0..1	healthcare commitment	relates to the provision of	1..*	healthcare activity
1	healthcare mandate	requires	1	healthcare commitment

Table 109 *(continued)*

1	healthcare provider	states	1..*	healthcare commitment
0..1	referral	asks for	1	healthcare commitment

Figure 120 — Healthcare commitment (UML representation)

11.2.11 Subject of care desire

Term: *subject of care desire*

Definition: desire expressed by the *subject of care* or the *subject of care proxy* regarding the performance of certain *healthcare activities*

NOTE In quality management [ISO 9000:2015] requirement is defined as "needs and expectations that is stated generally implied or obligatory". The expectations reflect the *subject of care's* desires.

EXAMPLES No blood transfusion, cultural or religious preference, do not resuscitate, allow natural death

Table 110 lists the associations of this concept; a UML representation of the concept is shown in Figure 121.

Table 110 — Associations of *subject of care desire*

Association from		Association name	Association to	
0..1	subject of care	expresses	0..*	subject of care desire
0..1	subject of care proxy	expresses	0..*	subject of care desire
0..*	subject of care desire	influences	0..*	healthcare mandate
0..*	subject of care desire	is considered during	1..*	healthcare needs assessment
0..*	subject of care desire	is recorded in	0..*	health record

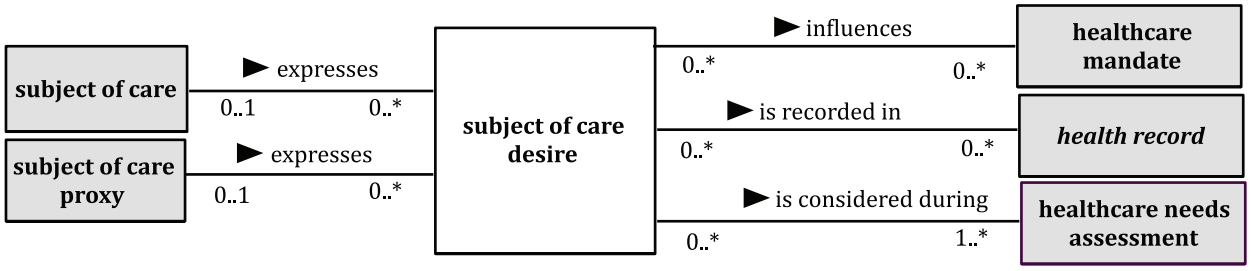

Figure 121 — Subject of care desire (UML representation)

11.3 Demand for care

Term: *demand for care*

Synonym: demand for healthcare

Definition: demand for *healthcare provider activities* expressed by a *healthcare actor*

NOTE 1 A *demand for care* may be expressed either by the *subject of care* or on their behalf.

NOTE 2 A *healthcare provider* may accept or decline a *demand for care*.

NOTE 3 A *demand for care* could result in a *healthcare assessment* concluding that no other *healthcare activity elements* (as *healthcare investigations* and/or *healthcare treatments*) should be performed.

EXAMPLES

An emergency call to a GP for a home visit at night.

A request for an appointment at a cardiology outpatient department.

A request for the intervention of a community nurse.

Table 111 lists the associations of this concept; a UML representation of the concept is shown in Figure 122.

Table 111 — Associations of *demand for care*

Specialization of	**Generalization of**
	referral
	request
	demand for initial contact

Association from		**Association name**	**Association to**	
1..*	demand for care	justifies	0..*	demand mandate
0..1	demand for care	asks for	1..*	healthcare provider activity
0..*	demand for care	concerns	1..*	healthcare matter
1	reason for demand for care	motivates	0..*	demand for care
1..*	healthcare actor	expresses	0..*	demand for care
1	healthcare provider	receives	1..*	demand for care
1	healthcare provider	accepts or denies	1..*	demand for care
0..*	healthcare professional	manages	0..*	demand for care
0..1	demand for care	triggers	0..1	care period mandate

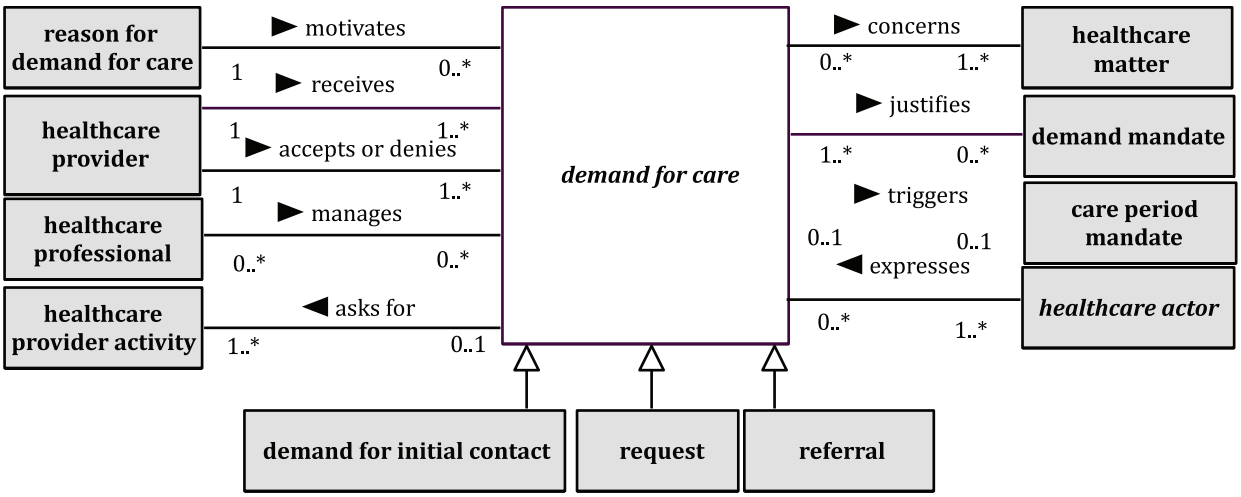

Figure 122 — Demand for care (UML representation)

11.3.1 Demand for initial contact

Term: demand for initial contact

Definition: first *demand for care* concerning one or more specific *health issues* to be assessed by a *healthcare provider*

Table 112 lists the associations of this concept; a UML representation of the concept is shown in Figure 123.

Table 112 — Associations of *demand for initial contact*

Specialization of	**Generalization of**
demand for care	

Association from		**Association name**	**Association to**	
0..1	demand for initial contact	results in	0..1	initial contact

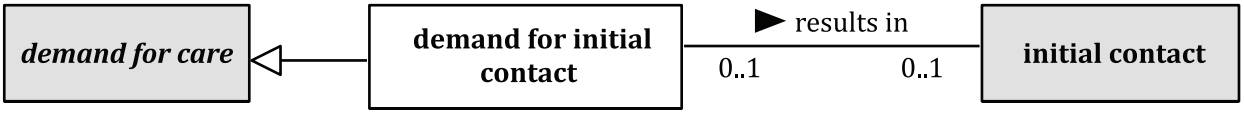

Figure 123 — Demand for initial contact (UML representation)

11.3.2 Referral

Term: *referral*

Definition: *demand for care* where a *healthcare professional* asks a *healthcare provider* to state a *healthcare commitment* for a *care period mandate*

NOTE An accepted *referral* transfers the continuity responsibility for the *health issues* specified in the *referral*.

EXAMPLE A *referral* from an orthopaedic surgeon to a rehabilitation service.

Table 113 lists the associations of this concept; a UML representation of the concept is shown in Figure 124.

Table 113 — Associations of *referral*

Specialization of	**Generalization of**
demand for care	

Association from		**Association name**	**Association to**	
0..1	referral	initiates	0..1	contact
1	healthcare professional	issues	0..*	referral
0..1	referral	asks for	1	healthcare commitment

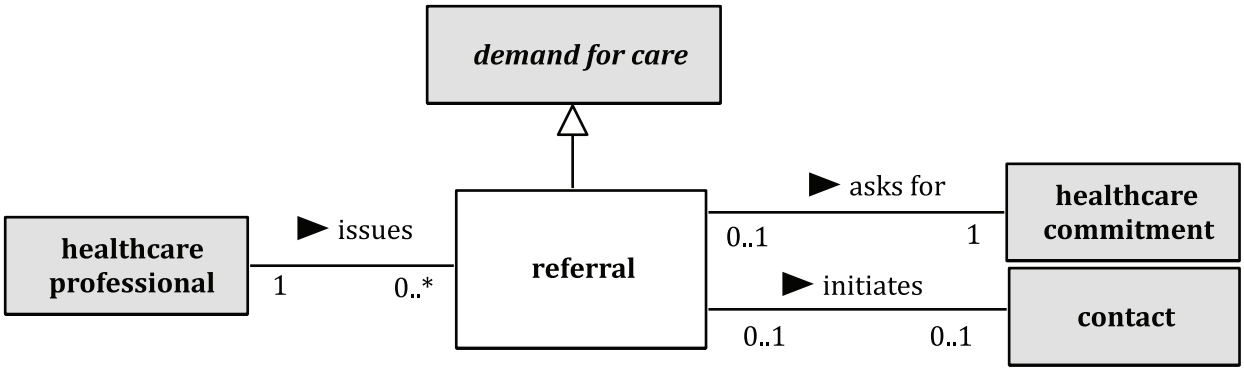

Figure 124 — Referral (UML representation)

11.3.3 Request

Term: *request*

Synonyms: order, healthcare provider activity request

Definition: *demand for care* where a *healthcare professional* asks a *healthcare provider* to perform one or more *healthcare provider activities*

NOTE 1 A request is put forward by a *healthcare professional* within a *healthcare process*.

NOTE 2 The responsibility for the requested *healthcare provider activities* is held by the performer but they will be performed under the *care period mandate* of the requester.

NOTE 3 A *healthcare provider* may accept or decline a *request* (order) to perform *healthcare activities*.

EXAMPLE *Request* for a *healthcare assessment*, an operation, a wheelchair, etc.

Table 114 lists the associations of this concept; a UML representation of the concept is shown in Figure 125.

Table 114 — Associations of *request*

Specialization of		**Generalization of**	
demand for care			
Association from		**Association name**	**Association to**
1	healthcare professional	issues	0..* request

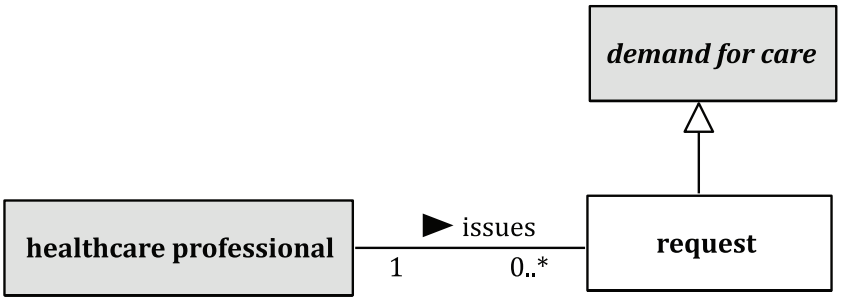

Figure 125 — Request (UML representation)

11.3.4 Reason for demand for care

Term: *reason for demand for care*

Definition: *subject of care* or a *subject of care proxy's* perception of *health needs* motivating a *demand for care*

NOTE There are needs for both direct (*healthcare investigating* and *healthcare treatment*) and indirect (*healthcare assessments*, *healthcare planning*, *healthcare evaluation*, etc.) *healthcare activities*.

Table 115 lists the associations of this concept; a UML representation of the concept is shown in Figure 126.

Table 115 — Associations of *reason for demand for*

Association from		Association name	Association to	
1	reason for demand for care	motivates	0..*	demand for care
0..*	health need	is background for	0..*	reason for demand for care
0..*	reason for demand for care	is expressed by	0..1	subject of care
0..*	reason for demand for care	is expressed by	0..*	subject of care proxy

Figure 126 — Reason for demand for care (UML representation)

12 Concepts related to information management

12.1 General

A model showing the associations between the concepts related to healthcare information management in continuity of care and the other concepts defined in this International Standard is shown in Figure 127. For further detail about the diagram notation, please refer to 0.7 in the Introduction.

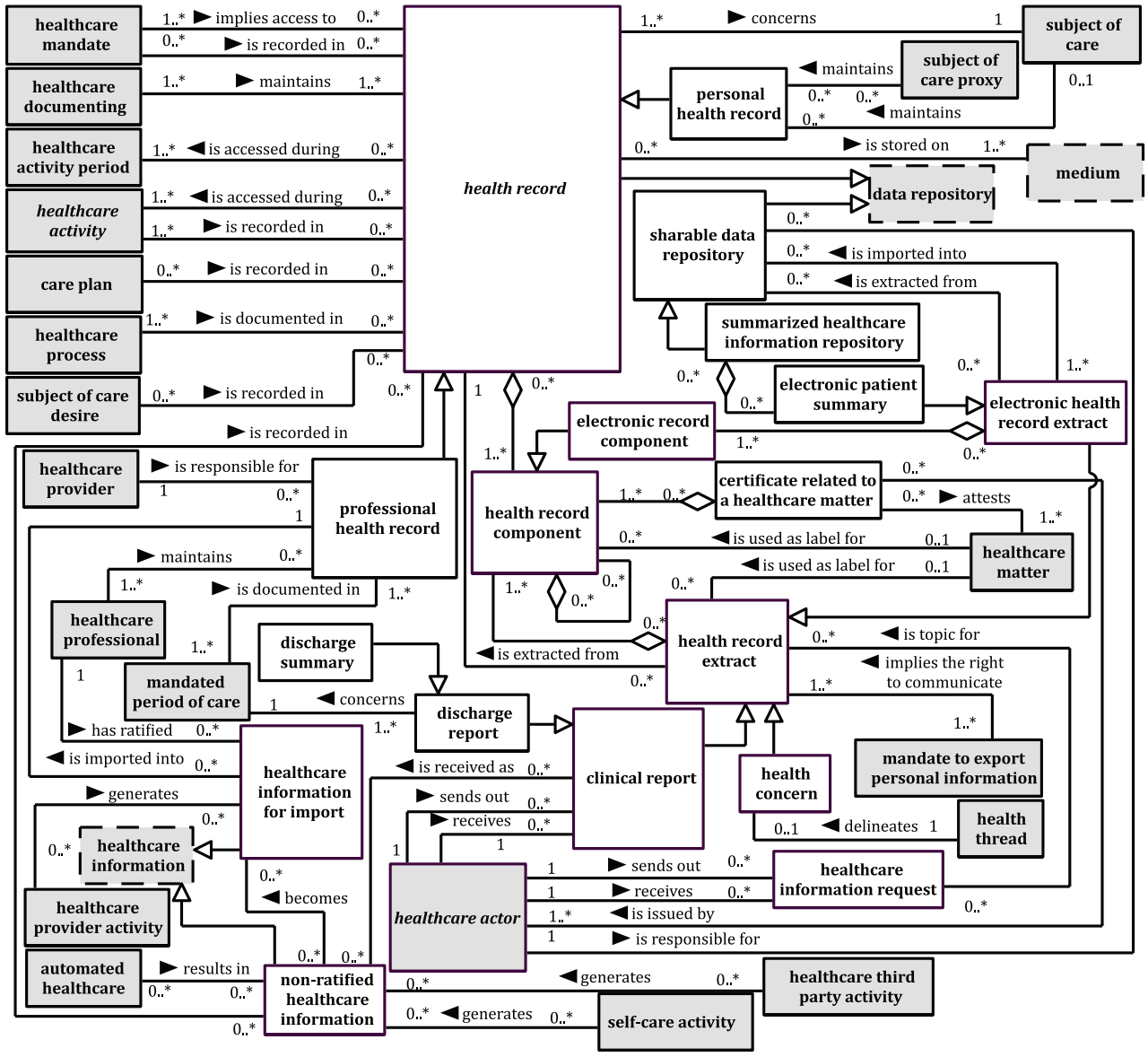

Figure 127 — Comprehensive UML diagram of concepts related to information management

12.2 Health record

Term: *health record*

Definition: *data repository* regarding the health and healthcare of a *subject of care*

NOTE 1 The term electronic health record may be used for a *health record* where all information is stored on electronic media. However, this concept is not formally defined in this International Standard.

NOTE 2 A *health record* may include, for example, medical records, dental records, social care records.

Table 116 lists the associations of this concept; a UML representation of the concept is shown in Figure 128.

Table 116 — Associations of *health record*

Specialization of	**Generalization of**
data repository	professional health record
	personal health record

Component of		**Aggregation of**	
		1..*	health record component

Association from		**Association name**	**Association to**	
1..*	health record	concerns	1	subject of care
0..*	health record	is accessed during	1..*	healthcare activity period
0..*	health record	is accessed during	1..*	healthcare activity
0..*	health record	is stored on	1..*	medium
1..*	healthcare activity	is recorded in	0..*	health record
0..*	healthcare mandate	is recorded in	0..*	health record
1..*	healthcare mandate	implies access to	0..*	health record
0..*	health record extract	is extracted from	1	health record
0..*	non-ratified healthcare information	is recorded in	0..*	health record
1..*	healthcare documenting	maintains	1..*	health record
1..*	healthcare process	is documented in	0..*	health record
0..*	care plan	is recorded in	0..*	health record
0..*	subject of care desire	is recorded in	0..*	health record

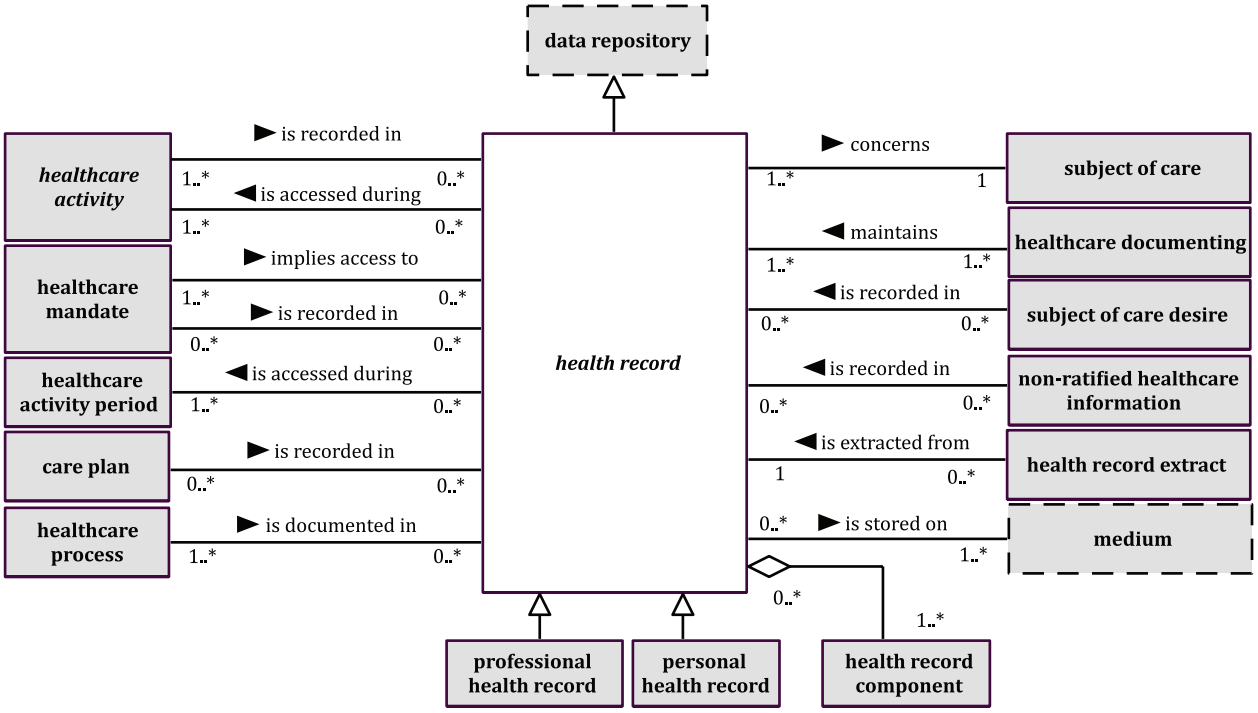

Figure 128 — Health record (UML representation)

12.2.1 Professional health record

Term: *professional health record*

Definition: *health record* held under the responsibility of one *healthcare provider* and maintained by one or several *healthcare professionals*

NOTE The responsible *healthcare provider* may allow the *subject of care* to access and/or offer contributions to the *professional health record*.

EXAMPLES *Health records* held at their surgery or at a health centre by a GP, by a medical specialist, by a nurse, in a hospital department at a patient's bedside, by a care team in an integrated clinical network, by a dentist.

Table 117 lists the associations of this concept; a UML representation of the concept is shown in Figure 129.

Table 117 — Associations of *professional health record*

Specialization of	**Generalization of**
health record	

Association from		**Association name**	**Association to**	
1	healthcare provider	is responsible for	0..*	professional health record
1..*	healthcare professional	maintains	0..*	professional health record
1..*	mandated period of care	is documented in	1..*	professional health record
0..*	healthcare information for import	is imported into	1	professional health record

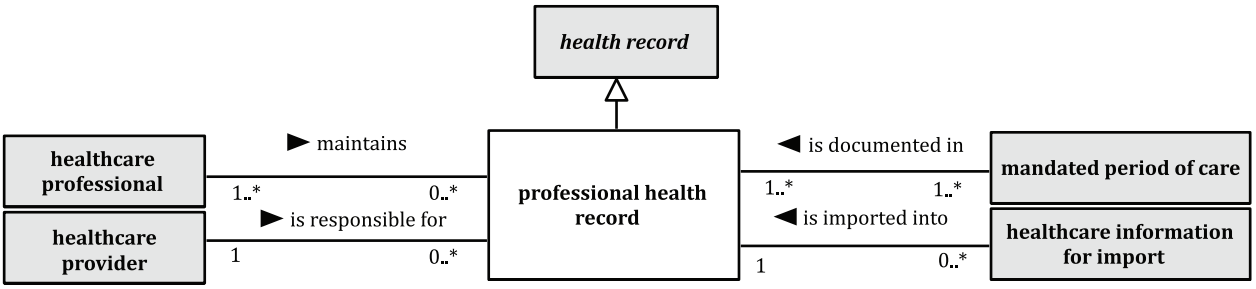

Figure 129 — Professional health record (UML representation)

12.2.2 Personal health record

Term: *personal health record*

Abbreviation: PHR

Definition: *health record* held and maintained by the *subject of care* or a *subject of care proxy*

NOTE A *subject of care* may allow any *healthcare actor* to access and/or offer contributions to the *personal health record*.

Table 118 lists the associations of this concept; a UML representation of the concept is shown in Figure 130.

Table 118 — Associations of *personal health record*

Specialization of		**Generalization of**		
health record				
Association from		**Association name**	**Association to**	
0..1	subject of care	maintains	0..*	personal health record
0..*	subject of care proxy	maintains	0..*	personal health record

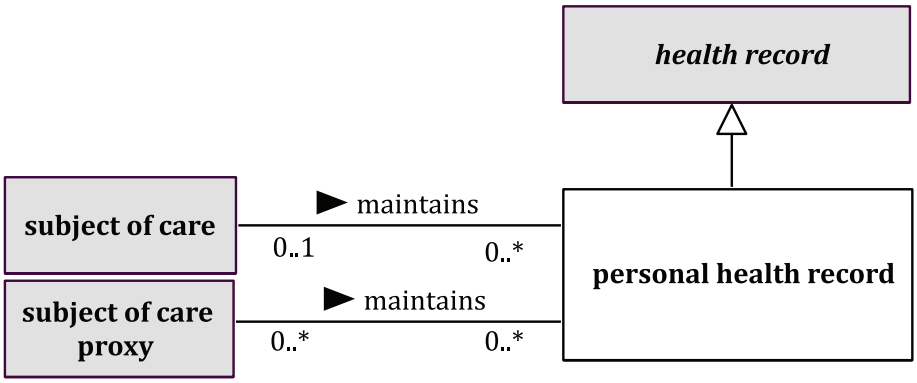

Figure 130 — Personal health record (UML representation)

12.2.3 Health record component

Term: *health record component*

Definition: part of a *health record* that is identifiable for the purposes of referencing and revision

NOTE 1 This International Standard defines one *health record component* specialization, the *electronic record component*. However, as the content of a *health record* is not limited to information in electronic format, the content of *health record components* may be in formats other than electronic.

NOTE 2 A *health record component* may itself result from an aggregation of multiple *health record components*.

Table 119 lists the associations of this concept; a UML representation of the concept is shown in Figure 131.

Table 119 — Associations of *health record component*

Specialization of		**Generalization of**	
		electronic record component	
Component of		**Aggregation of**	
0..*	health record	0..*	health record component
0..*	health record extract		
0..*	health record component		
0..*	certificate related to a healthcare matter		

Association from		**Association name**	**Association to**	
0..1	healthcare matter	is used as label for	0..*	health record component

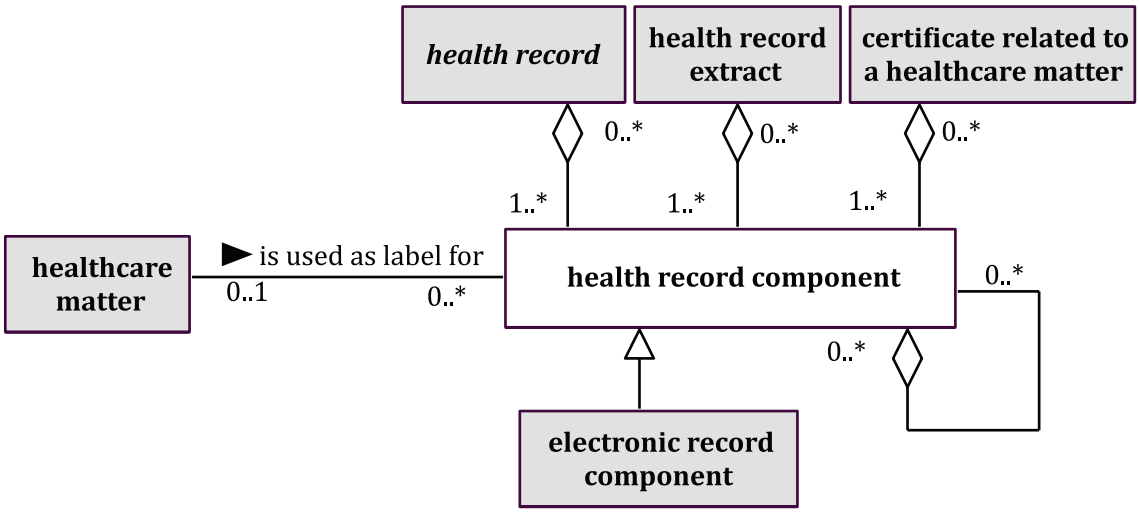

Figure 131 — Health record component (UML representation)

12.2.4 Electronic health record component

Term: *electronic health record component*

Synonyms: record component, electronic record component

Definition: *health record component* which only includes information in electronic format

NOTE 1 *Electronic health record component* correlates to record component in ISO 13606.

NOTE 2 In EN 13940–1:2007 record component was the preferred term for this concept.

Table 120 lists the associations of this concept; a UML representation of the concept is shown in Figure 132.

Table 120 — Associations of *electronic health record component*

Specialization of		**Generalization of**	
health record component			
Component of		**Aggregation of**	
0..*	electronic health record extract		

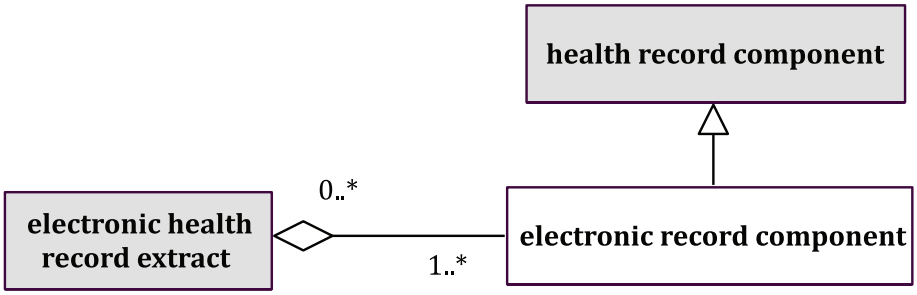

Figure 132 — Electronic health record component (UML representation)

12.3 Sharable data repository

Term: *sharable data repository*

Definition: *data repository* containing exclusively *electronic health record extracts,* accessible for duly authorized *healthcare actors* independent of their organizational affiliation and placed under the custody of a *healthcare actor*

NOTE 1 A *sharable data repository* has to be placed under the custody of a *healthcare actor* in order to ensure and maintain its consistency.

NOTE 2 In EN 13940–1:2007 *sharable data repository* was defined as '*electronic health record* containing exclusively *sharable data*, placed under the custody of a *health care party*, to whom a *continuity facilitator mandate* has been delivered'.

Table 121 lists the associations of this concept; a UML representation of the concept is shown in Figure 133.

Table 121 — Associations of *sharable data repository*

Specialization of		**Generalization of**	
data repository		summarized healthcare information repository	
Association from		**Association name**	**Association to**
1	healthcare actor	is responsible for	0..* sharable data repository
1..*	electronic health record extract	is imported into	0..* sharable data repository
0..*	electronic health record extract	is extracted from	0..* sharable data repository

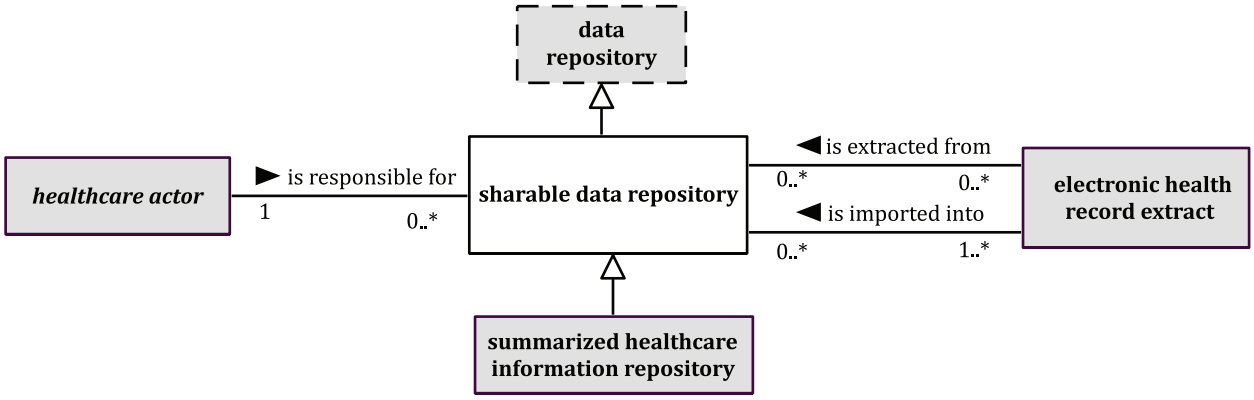

Figure 133 — Sharable data repository (UML representation)

12.4 Summarized healthcare information repository

Term: *summarized healthcare information repository*

Synonym: patient summary repository

Definition: *data repository* containing summarized information for healthcare coordination and the continuity of care

Table 122 lists the associations of this concept; a UML representation of the concept is shown in Figure 134.

Table 122 — Associations of *summarized healthcare information repository*

Specialization of		**Generalization of**	
shareable data repository			
Component of		**Aggregation of**	
		0..*	electronic patient summary

Figure 134 — Summarized healthcare information repository (UML representation)

12.5 Health record extract

Term: *health record extract*

Definition: part or all of a *health record* extracted for the purpose of communication

NOTE 1 This International Standard defines one *health record extract* specialization - the *electronic record extract*. However, as the content of a *health record* is not limited to information in electronic format, the content of *health record extracts* may be in formats other than electronic.

Table 123 lists the associations of this concept; a UML representation of the concept is shown in Figure 135.

Table 123 — Associations of *health record extract*

Specialization of		**Generalization of**	
		clinical report	
		electronic health record extract	
		health concern	
Component of		**Aggregation of**	
		1..*	health record component

Association from		**Association name**	**Association to**	
0..*	health record extract	is extracted from	1	health record
1..*	mandate to export personal information	implies the right to communicate	1..*	health record extract
0..1	healthcare matter	is used as label for	0..*	health record extract
0..*	healthcare information request	is topic for	0..*	health record extract

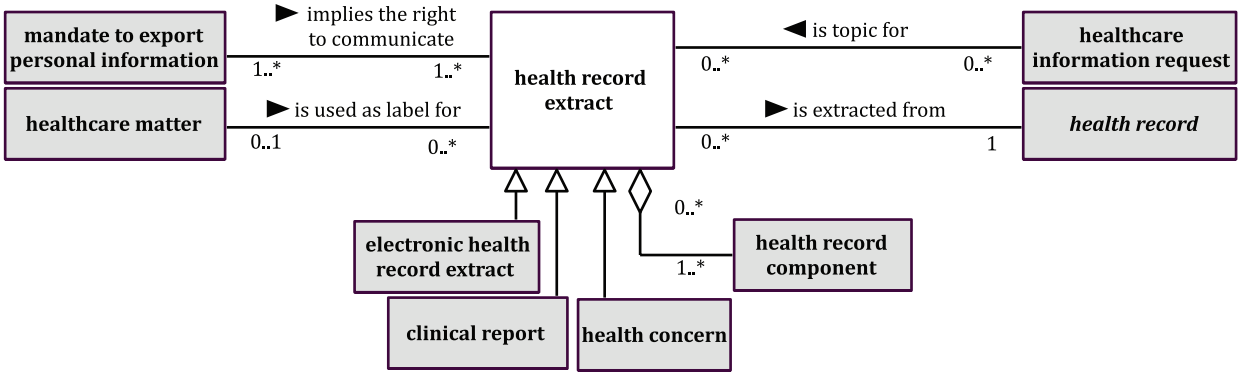

Figure 135 — Health record extract (UML representation)

12.5.1 Electronic health record extract

Term: *electronic health record extract*

Synonym: EHR extract

Abbreviation: EHR extract

Definition: *health record extract* consisting solely of *electronic record components*

NOTE 1 Provisions for the communication of *electronic health record extracts* are to be found in ISO 13606.

NOTE 2 In EN 13940–1:2007 EHR extract was the preferred term for this concept.

Table 124 lists the associations of this concept; a UML representation of the concept is shown in Figure 136.

Table 124 — Associations of *electronic health record extract*

Specialization of		**Generalization of**	
health record extract		electronic patient summary	
Component of		**Aggregation of**	
		1..*	electronic record component

Table 124 *(continued)*

Association from		Association name	Association to	
1..*	electronic health record extract	is imported into	0..*	sharable data repository
0..*	electronic health record extract	is extracted from	0..*	sharable data repository

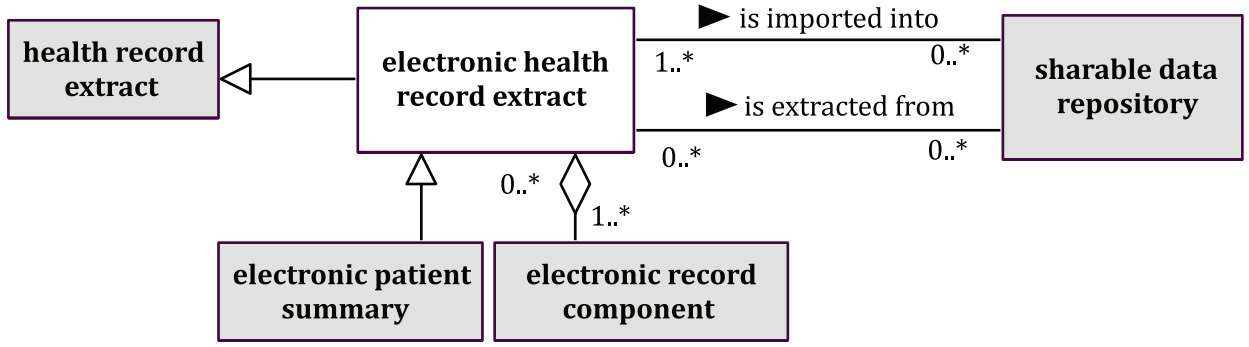

Figure 136 — Electronic health record extract (UML representation)

12.5.2 Electronic patient summary

Term: *electronic patient summary*

Definition: *electronic health record extract* containing essential *healthcare information* intended for specific uses

EXAMPLES epSOS patient summary (EU), clinical summary (US), continuity care record (US), an *electronic patient summary* providing a *healthcare professional* with essential information needed for coordinated healthcare

Table 125 lists the associations of this concept; a UML representation of the concept is shown in Figure 137.

Table 125 — Associations of *electronic patient summary*

Specialization of		Generalization of	
electronic health record extract			
Component of		**Aggregation of**	
0..*	summarized healthcare information repository		

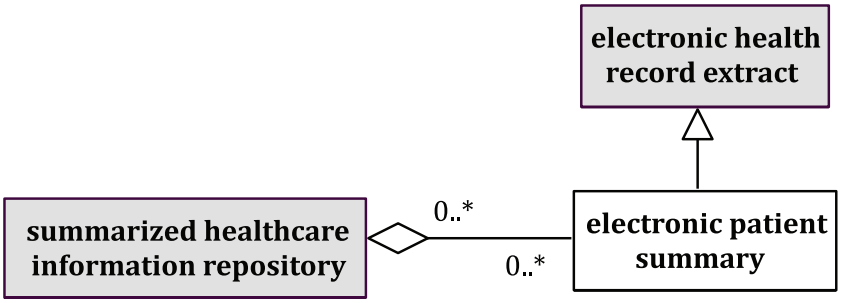

Figure 137 — Electronic patient summary (UML representation)

12.5.3 Clinical Report

Term: *clinical report*

Definition: *health record extract* conveying specifically focused healthcare information in order to fulfil current information needs of the recipient

EXAMPLES lab report, X-Ray report

Table 126 lists the associations of this concept; a UML representation of the concept is shown in Figure 138.

Table 126 — Associations of *clinical report*

Specialization of	**Generalization of**
health record extract	discharge report

Association from		**Association name**	**Association to**	
0..*	clinical report	is received as	0..*	non-ratified healthcare information
1	healthcare actor	sends out	0..*	clinical report
1	healthcare actor	receives	0..*	clinical report

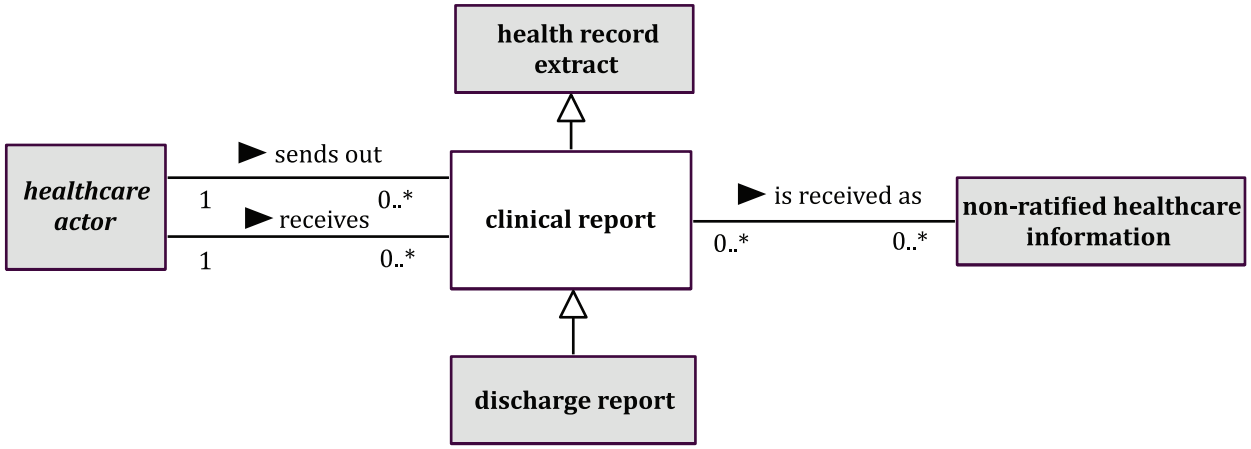

Figure 138 — Clinical report (UML representation)

12.5.3.1 Discharge report

Term: *discharge report*

Definition: *clinical report* concerning a completed, *mandated period of care*

EXAMPLE Discharge letter

Table 127 lists the associations of this concept; a UML representation of the concept is shown in Figure 139.

Table 127 — Associations of *discharge report*

Specialization of	**Generalization of**
clinical report	discharge summary

Table 127 *(continued)*

Association from		Association name	Association to	
1..*	discharge report	concerns	1	mandated period of care

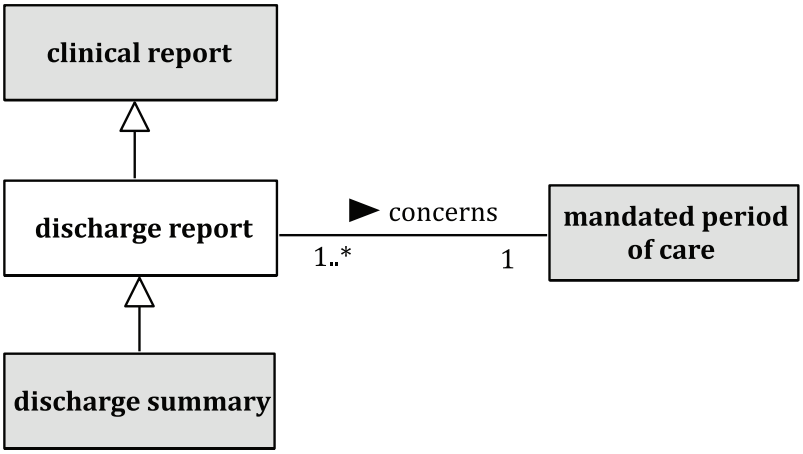

Figure 139 — Discharge report (UML representation)

12.5.3.2 Discharge summary

Term: *discharge summary*

Definition: *discharge report* summarizing a *mandated period of care*

NOTE 1 A *discharge summary* may be provided to the *subject of care*.

NOTE 2 One *mandated period of care* may be immediately followed by another; the next mandated *healthcare provider* will then be a main recipient of the *discharge summary*.

NOTE 3 *Discharge summaries* are often meant to be processed so as to categorize hospital stays according to a statistically designed classification (such as the Diagnosis-Related Groups (DRGs) or other systems), usually for funding or epidemiological purposes.

EXAMPLES

'Uniform Hospital Discharge Data Set' and 'Uniform Ambulatory Medical Care Minimum Data Set' in the USA

'Résumé de sortie standardisé' (RSS) or 'Résumé d'Unité Médicale' (RUM) in France

Nursing minimal data set (NMDS), etc.

Table 128 lists the associations of this concept; a UML representation of the concept is shown in Figure 140.

Table 128 — Associations of *discharge summary*

Specialization of	Generalization of
discharge report	

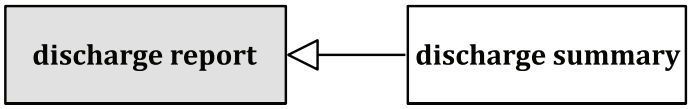

Figure 140 — Discharge summary (UML representation)

12.5.3.3 Non-ratified healthcare information

Term: *non-ratified healthcare information*

Definition: *healthcare information* the relevance of which has not been assessed and explicitly stated as valid by a *healthcare professional*

NOTE 1 *Healthcare information* that has been received and is proposed for incorporation in a *professional health record* may not yet have been reviewed for validity or context by the *healthcare professional*, and as such its' accuracy may remain arguable. In this respect, clinical ratification differs both from attesting information for the needs of an audit trail, or from committing information in the perspective of sending out messages containing healthcare information, outlined in ISO 13606-1:2008.

NOTE 2 Regardless of the technical process meant practically, *healthcare information* cannot be 'inserted' into a *professional health record* unless ratified by a *healthcare professional*. Until a decision is made regarding their insertion or rejection, they are held in a secure temporary storage. An exception to this would be when a *healthcare professional* would directly import *healthcare information* from a *sharable data repository* into the local *health record* they hold. In the case where this import resulted from a request to the *healthcare actor* in the custody of whom the *sharable data repository* is placed, that *healthcare information* would then need validation.

Table 129 lists the associations of this concept; a UML representation of the concept is shown in Figure 141.

Table 129 — Associations of *non-ratified healthcare information*

Specialization of	**Generalization of**
healthcare information	

Association from		**Association name**	**Association to**	
0..*	non-ratified healthcare information	is recorded in	0..*	health record
0..*	non-ratified healthcare information	becomes	0..*	healthcare information for import
0..*	clinical report	is received as	0..*	non-ratified healthcare information
0..*	self-care activity	generates	0..*	non-ratified healthcare information
0..*	healthcare third party activity	generates	0..*	non-ratified healthcare information
0..*	automated healthcare	results in	0..*	non-ratified healthcare information

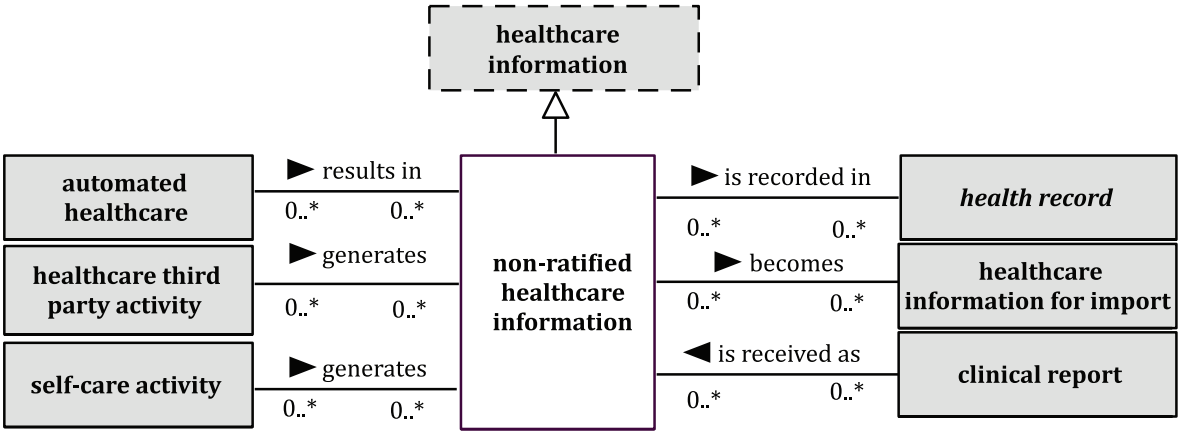

Figure 141 — Non-ratified healthcare information (UML representation)

12.5.3.4 Healthcare information for import

Term: *healthcare information for import*

Definition: *healthcare information* that is a candidate for import into a *professional health record* after a *healthcare professional* has confirmed its clinical relevance to that professional health record

Table 130 lists the associations of this concept; a UML representation of the concept is shown in Figure 142.

Table 130 — Associations of *healthcare information for import*

Specialization of	**Generalization of**
healthcare information	

Association from		**Association name**	**Association to**	
0..*	healthcare information for import	is imported into	1	professional health record
0..*	non-ratified healthcare information	becomes	0..*	healthcare information for import
1	healthcare professional	has ratified	0..*	healthcare information for import
0..*	healthcare provider activity	generates	0..*	healthcare information for import

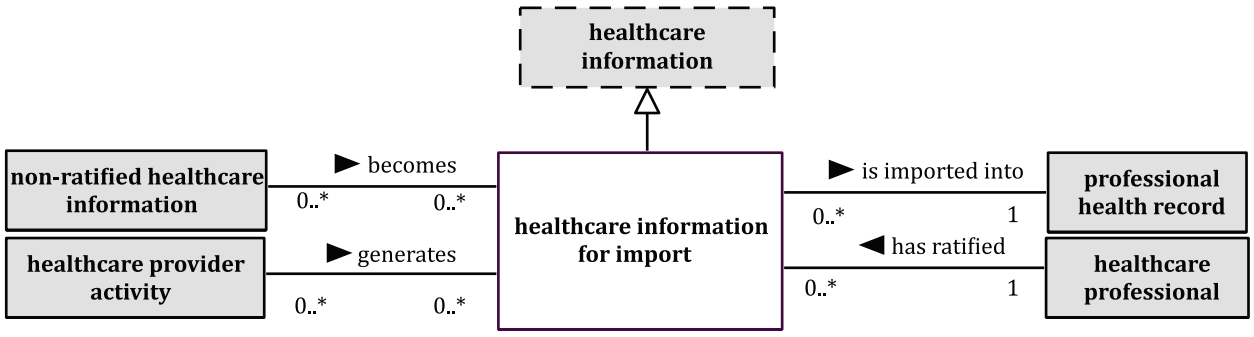

Figure 142 — Healthcare information for import (UML representation)

12.5.4 Health concern

Term: *health concern*

Definition: *health record extract* that includes all *health record components* associated with a *health thread* for a specific concern

NOTE 1 A concern is gathered information to support continuity of care for a *subject of care*. A *health thread* can include *healthcare activities*, *health conditions*, *healthcare activity planning*, *activity management*, evaluations and assessments. Thereby, all information needed for continuity of care for an individual *subject of care* can be covered by a *health concern*.

NOTE 2 *Health concerns* can be constructed to support continuity of care for *healthcare processes*, *clinical processes* and accumulations/associations of *clinical processes*. This means that concerns can relate to *episodes of care*, *contacts*, chronic disease management, multiple chronic disease management, etc.

NOTE 3 *Health concerns* can be represented and labelled in EHR as extracts or components.

NOTE 4 *Health concern* is closely related to the "concern tracking" based on HL7 standards.

EXAMPLE Concern tracker (HL7).

Table 131 lists the associations of this concept; a UML representation of the concept is shown in Figure 143.

Table 131 — Associations of *health concern*

Specialization of		**Generalization of**		
health record extract				
Association from		**Association name**	**Association to**	
1	health thread	delineates	0..1	health concern

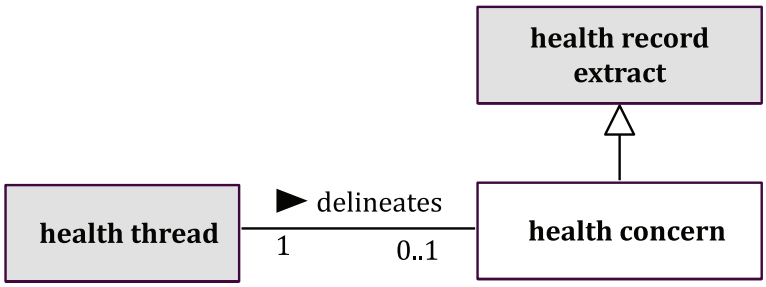

Figure 143 — Health concern (UML representation)

12.5.5 Healthcare information request

Term: *healthcare information request*

Synonym: specific healthcare information request

Definition: request sent out by a *healthcare actor* to another *healthcare actor* for specific *healthcare information* needed for the provision of healthcare to a *subject of care*

NOTE 1 In order to fulfil the request, a *mandate to export personal information* is needed.

NOTE 2 In EN 13940–1:2007 specific clinical information request was the preferred term for this concept.

Table 132 lists the associations of this concept; a UML representation of the concept is shown in Figure 144.

Table 132 — Associations of *healthcare information request*

Association from		Association name	Association to	
0..*	healthcare information request	is topic for	0..*	health record extract
1	healthcare actor	sends out	0..*	healthcare information request
1	healthcare actor	receives	0..*	healthcare information request

Figure 144 — Healthcare information request (UML representation)

12.6 Certificate related to a healthcare matter

Term: certificate related to a healthcare matter

Definition: official document issued by a healthcare actor attesting healthcare matters relating to a subject of care

EXAMPLES Birth certificate, death certificate, health certificate, health insurance certificate

Table 133 lists the associations of this concept; a UML representation of the concept is shown in Figure 145.

Table 133 — Associations of *certificate related to a healthcare matter*

Component of		Aggregation of	
		1..*	health record component

Association from		Association name	Association to	
0..*	certificate related to a healthcare matter	attests	1..*	healthcare matter
0..*	certificate related to a healthcare matter	is issued by	1..*	healthcare actor

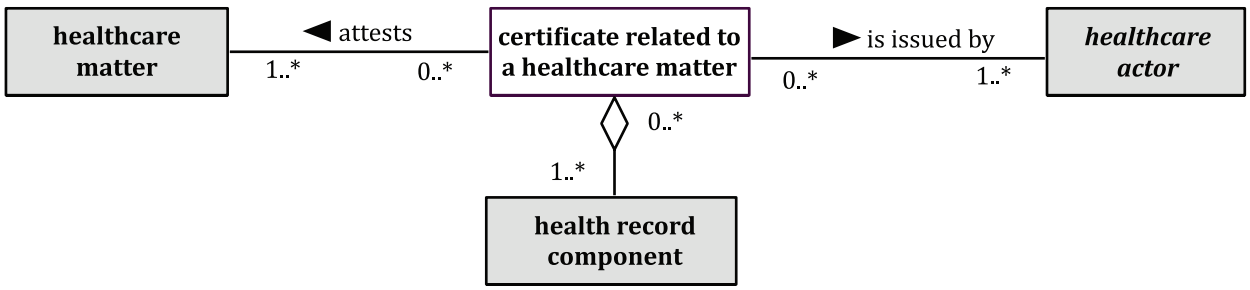

Figure 145 — Certificate related to a healthcare matter (UML representation)

13 Conformance

13.1 Where a concept defined in this International Standard is used it shall be labelled by the preferred term or a synonym, acronym or abbreviation defined in this International Standard.

13.2 Where a term labelling a concept defined in this International Standard is used, it shall represent that concept and therefore have the same meaning and definition.

13.3 Where specializations of the concepts defined in this International Standard are used all the relationships between these specializations, as defined in the normative provisions of this International Standard, including their relationship, shall be used. Multiplicities shall be within the limits specified in this International Standard.

Annex A
(informative)

Framework for the normative concepts in this International Standard

A.1 General

This annex provides guidance and support for the understanding and application of this system of concepts needed to achieve continuity of care.

Semantic interoperability is essential for continuity of care. Models and concepts representing all aspects of the content and context of the healthcare services provide the basis for such semantic interoperability.

Healthcare is provided through activities in the healthcare and the clinical processes reflecting the interaction between a subject of care and healthcare professionals.

This annex explains the process approach for context and also of the traceability between this context of processes and the content represented by the normative concepts of this International Standard. The traceability is shown by illustrations of the relations between the normative concepts and two different kinds of illustrative models (healthcare/clinical process model and enterprise/information area model). This annex and the two models are supportive guidance and do not contain normative requirements for conformance to the standard.

Clause A.2 in this annex gives an overview of a general process approach applied in the development of this International Standard.

Clause A.3 discusses the order in which activities are performed.

Clause A.4 gives an overview of the types of processes in healthcare organizations as identified in this International Standard.

Clause A.5 presents a healthcare/clinical process model compatible with this International Standard.

An analysis of the relations between the basic clinical concepts of this International Standard and the model of the healthcare/clinical process is given in A.6; this clarifies traceability of the clinically oriented concepts to the clinical context.

Clause A.7 gives further traceability for non-clinical concepts in the broader context of health and care. This clause gives traceability of all clauses of concepts to an information area model that includes clinical context with the supporting and managing areas around it.

A.2 Processes in general

The generic definition of a process, outlined in ISO 9000:2015, is a “set of interrelated or interacting activities that use inputs to deliver an intended result”.

Processes are built up by activities that influence process objects. Processes can be aggregated and/or subdivided into different parts that can be considered as processes by themselves. The flow indicated by arrows in a process model represents values successively added to the process object and not a time sequence, which is usually described in a workflow model.

A characteristic of a process is that the activities carried out influence an object, representing the inputs that are then, as process objects, transformed into outputs. The resources used to deliver the activities

of a process may also be called inputs. Since the term input may be used to represent concepts other than the process object at the start, it is important that these kinds of inputs are clearly differentiated:

- the primary process input – the object processed, the transformation of which will produce the 'major' output (i.e. healthcare services) as the result of a clinical process
- the secondary resource inputs that are utilized in the process activities.

The definition and scope of a process depend upon the defined inputs and targeted outputs of the process objects.

The result of a process is defined as an output (ISO 9000:2015). The product may be a service if the results are not tangible. The products/services provided are received by the main customers of that organization.

When a process is subdivided, the output of a given part of that process (the process object after the value added by that part) often leads to it being an input to a following part of the complete process. The service received by a customer is the end result of the complete process.

Figure A.1 shows the general schematic representation of a process, with inputs, nested activities/processes, management, resource supply and outputs.

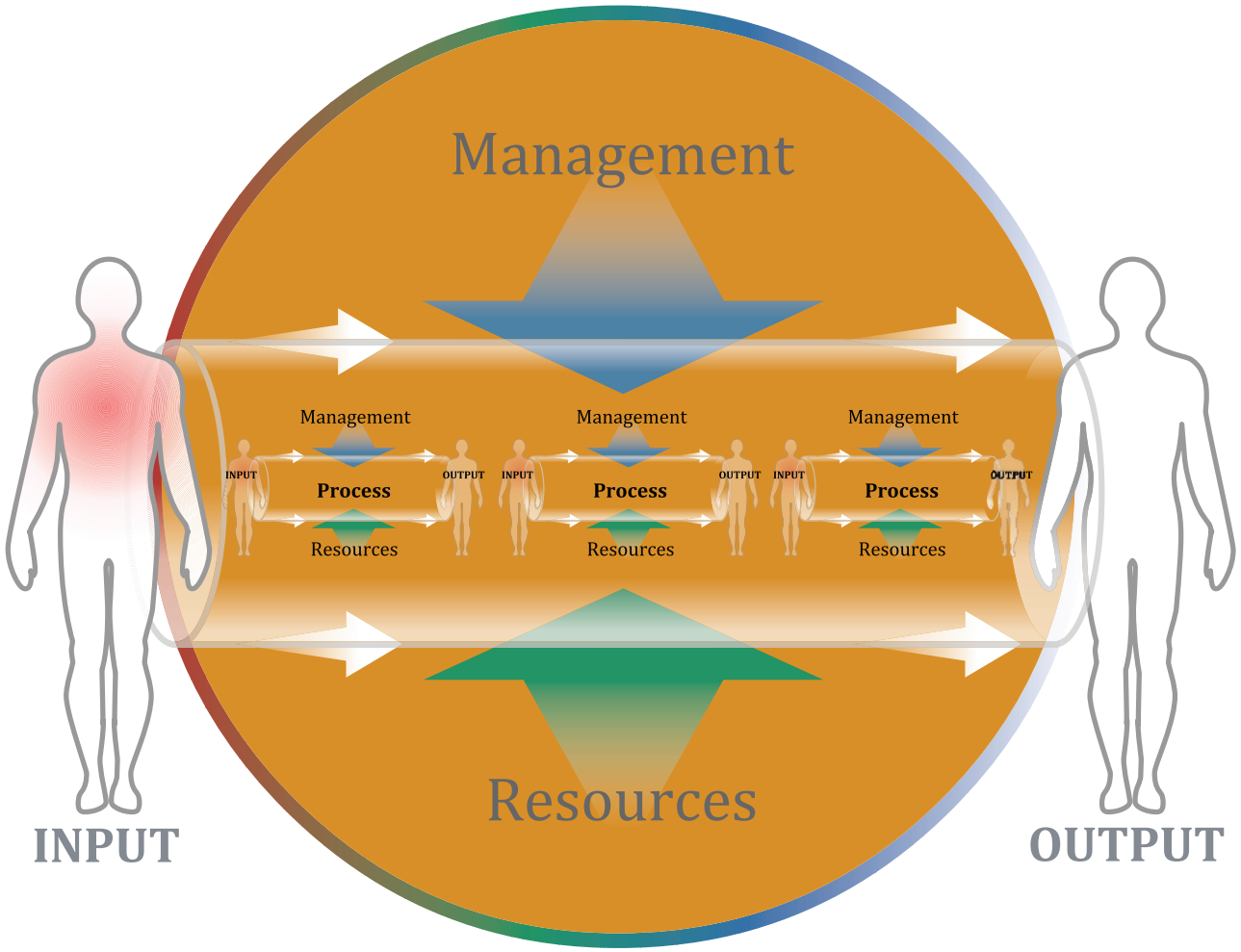

Figure A.1 — Schematic general process

In any organization many kinds of processes can be identified and defined by

- their inputs and outputs,

- the activities included, and
- the value these activities add to the process object in the transformation of the inputs.

In general there are certain kinds of processes that are more important for an enterprise sector when it comes to fulfilling the requirements of the main customers. These processes are sometimes called the core processes.

One method to describe processes is to use a modelling technique. In general, a process model describes

- the inputs (the primary objects processed),
- the activities that transform inputs,
- the life cycle of the activities during that transformation, and
- the resulting outputs after the values from the activities have been added.

A.3 Workflow in general

A workflow is the order in which the activities in a process are performed and as such a workflow is a time-related perspective of the sequence of the activities in a corresponding process. A workflow also identifies the participants (actors) and their roles in the process. Roles, like all the other concepts in this document, are defined at a very general, conceptual level, for instance, function or position, allowing them to be further specialized for specific purposes such as security and access control as and when required. These specializations may properly be defined by other standards to support implementation. Similarly, Workflow is also not defined here, and details as to how to perform specific healthcare / clinical/ informatics processes are not covered by this International Standard.

A.4 Types of processes and workflow in healthcare

In this International Standard a *healthcare organization* is defined as a '*healthcare provider* having an *organization role*. A healthcare provider performs *healthcare activities*. Three main types of processes in healthcare organizations have been identified in the work with this International Standard:

- healthcare and clinical processes;
- healthcare research processes; and
- healthcare educational processes.

A.4.1 Healthcare and clinical processes

The main operations in all healthcare organizations are related to the interaction between subjects of care and healthcare professionals. A healthcare process could be motivated by any health issue (representing a health state as the process object, described as an observed aspect of the health state) and include any set of activities related to the interaction between a subject of care and healthcare professionals. It can be subdivided into parts or aggregated to provide comprehensive care from the subject's of care perspective.

The main "outputs" in healthcare are healthcare services (the combined results of clinical processes). The subject of care is the receiver of these healthcare services as they improve or maintain the health state of that subject of care.

Continuity of care, clinical process knowledge management and keeping the subject of care as the focus are important quality aspects of healthcare services. To support good quality care a specialized type of healthcare process with specific characteristics is defined as a clinical process.

The clinical processes are comprehensive from the subject of care's perspective and consider the complete care related to the specified health issues considered to be health problems. For example,

the complete chain of care including primary care, care at hospitals, rehabilitation and medication (regardless of the organizational units that deliver the service) for a subject of care following a stroke could be defined as a clinical process.

The clinical processes can be identified so as to give prerequisites for an organization to fulfil their requirements and objectives, including continuity of care and other quality characteristics related to process management in their quality management system. The clinical processes represent the clinical context where activities can be coordinated from the subject of care's health need perspective.

For continuity of care the availability and reliability of the information shared is of great importance. The information 'container' labelling all relevant information for a clinical process is defined as a *health concern* for a *clinical process* in this International Standard.

Like all kinds of processes the healthcare- and clinical processes are dependent upon management and resource support; as shown in Figure A.2.

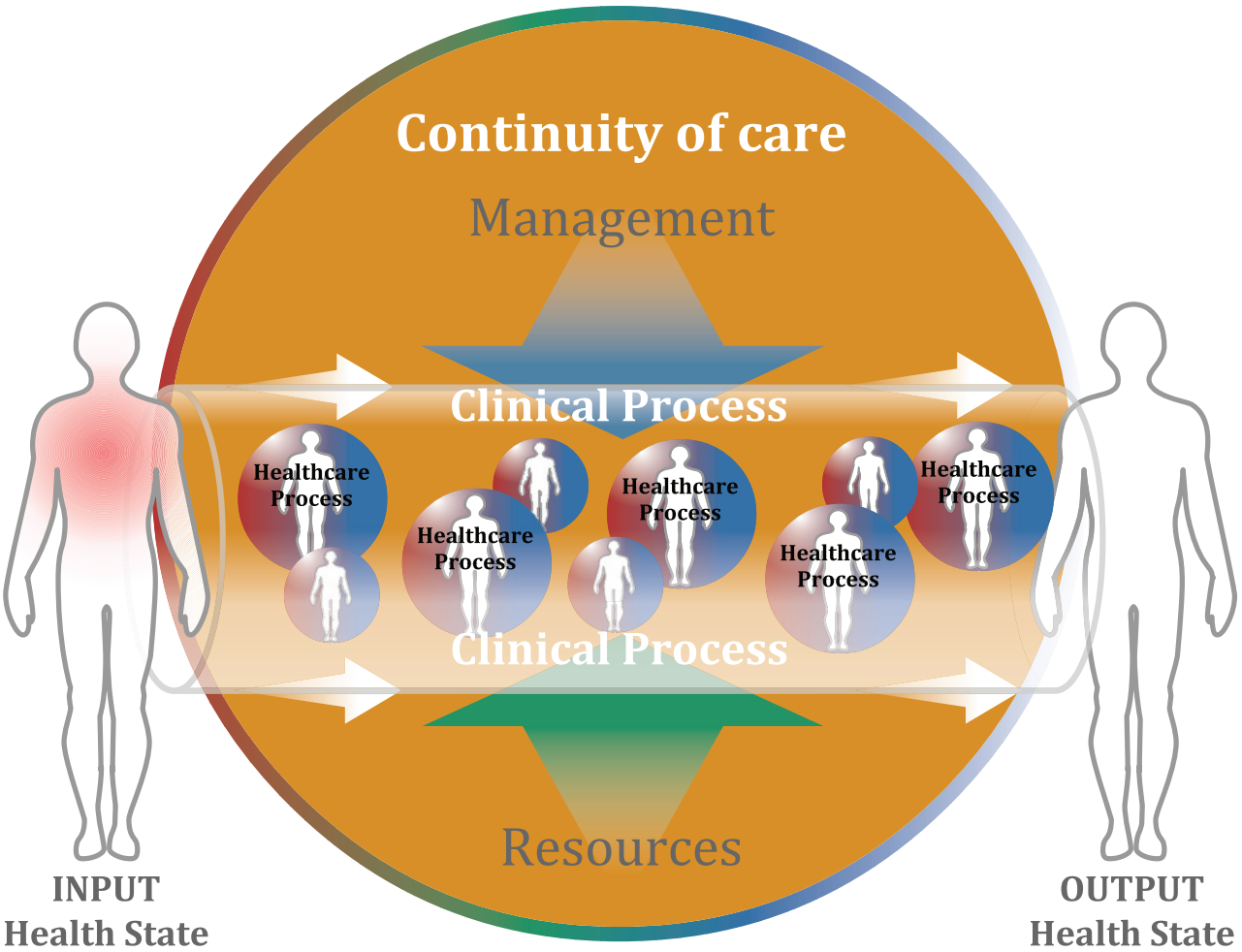

Figure A.2 — The clinical process in continuity of care

A.4.2 Healthcare research process

The healthcare research process is a type of process in some healthcare organizations such as university hospitals with an objective to contribute to clinical knowledge in general.

These types of processes are not within the scope of this International Standard.

A.4.3 Healthcare educational process

Another type of process in some healthcare organizations is the healthcare educational process with the aim to introduce and develop the knowledge and skills for *healthcare*.

Continuous competence development is included in all healthcare organizations and integrated in their organizational resource management approach.

As such, the healthcare educational processes encompass the basic education for healthcare actors.

These types of processes are not within the scope of this International Standard.

A.4.4 Workflow in healthcare

In healthcare and from the perspective of continuity of care, the workflow related to a *healthcare* or *clinical process* describes how and in which order care providers (singularly or as an organization) are given, take responsibility for and perform activities included in a *care plan*.

Workflow is not defined within this International Standard.

A.5 The healthcare/clinical process model

In the development of this International Standard, a generic model of healthcare and clinical processes has been used. The rationale for this is to give the clinical context, an overview of concept relations and provide traceability of the concepts for continuity of care to the clinical context.

A clinical and/or a healthcare 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 this International Standard is shown in Figure A.3

The clinical context described in this chosen healthcare/clinical process model may not be the choice for representing details in all healthcare systems. As the model is informative the use of this model should be limited to the aspects found relevant within each system.

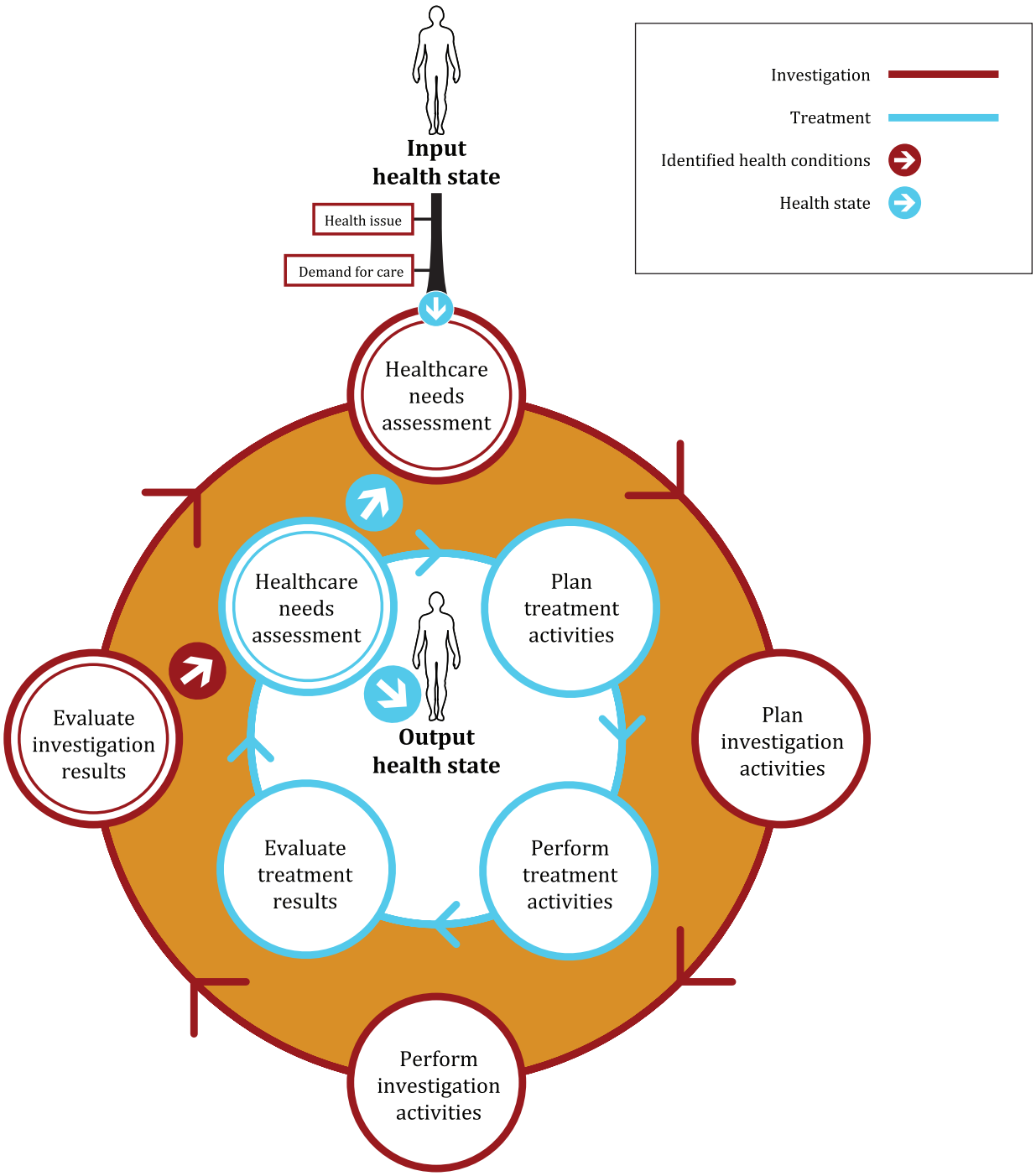

Figure A.3 — Main concepts of a clinical process

A.6 Traceability of concepts — Interrelations between concepts and healthcare/clinical process model

The provision of a healthcare service (as the result of a clinical process) has a complex context. A system of concepts that draws together the basis for semantic interoperability and supports continuity of care is required to cover many aspects from different perspectives.

This International Standard applies a modelling technique to achieve traceability, show the contextual interrelations, their comprehensiveness and provide a common understanding of the included concepts. This clause of the annex includes a description and analysis of the healthcare/clinical process model

presented in A.5. The traceability and interrelations of the different concepts are further described by a model of the enterprise/information areas that influence the core healthcare/clinical process in the following A.7.

The aims for these models are to provide context and demonstrate how concepts can be derived and explained from analysis of the clinical work. The normative concepts in this International Standard are systematically interrelated. These interrelations are further illustrated, both between the single concepts in each category/clause (illustrated by the UML-diagrams in the normative part) and between the groups of concepts in each category (illustrated by the relations to the two models in this annex).

The normative textual definitions and interrelations are mapped using their relations to the healthcare/clinical process and enterprise/information area models respectively. Analysis of the operations in the clinical processes can be used as a basis for a comprehensive system of concepts to support continuity of care. This International Standard has a primary focus upon the *clinical process* on the assumption that this is an effective approach to support continuity of care.

The clinical process model (Figure A.3) 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).

Figure A.4 shows a schematic version of the healthcare/clinical process model from A.5 with references to the normative clauses in this International Standard.

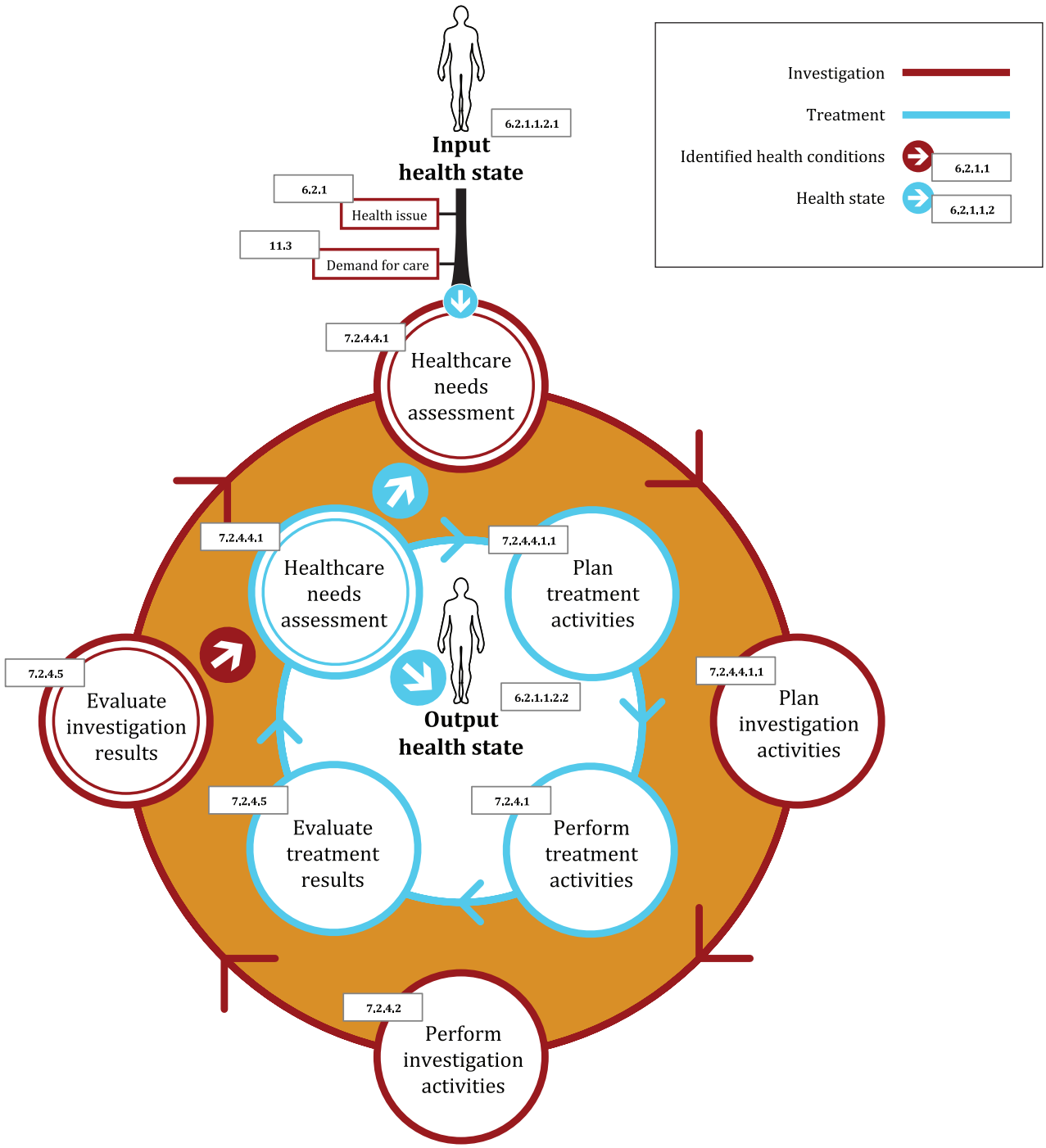

Figure A.4 — Main concepts of a clinical process showing clause references

A.6.1 Basic concepts and steps in the healthcare/clinical process model

A.6.1.1 Main concepts

The model of healthcare/clinical process describes:

- the *process input* expressed as health issues;
- the *health conditions* representing the transformation of the process input (the value added by the activities during the process) related to the goals and / or objectives;

- the *healthcare activities* used; and
- the resultant *process output* also expressed as health issues.

Concepts concerning the clinical content as well as the clinical context can be identified in a traceable way from this model.

A.6.1.2 Healthcare/clinical process input and output – the health state of a subject of care

Activities in any process influence an object. That object is represented as the inputs that are then transformed into outputs.

The primary process input, as the focus of a *healthcare* or a *clinical process*, is the *health state* of a *subject of care*. It is the health state as the holistic concept for the health of a person that is the primary concern for a clinical process. It will be influenced (i.e. improved, stabilized or have its deterioration slowed down) by *healthcare activities.*

The *health state* has many aspects; each of which can be perceived and described as a *health condition.*

The final outcome of this comprehensive clinical process is the *health state* of the *subject of care* after the influence of the activities in the process as the *process output* perceived and described as new *health conditions.*

A.6.1.3 Health conditions in a healthcare process or clinical process

During a *healthcare/clinical process*, several *health conditions* (existing or potential observations of a subject of care's *health state*) are described. A wide range of different aspects of the complex and holistic *health state* can be observed.

The *health issue* initiating a clinical process is commonly a *health condition* as felt by the subject of care and regarded by them as a *health problem*. This triggers a demand for care (*demand for initial contact*) and leads to the *initial contact* in a *clinical process*.

Once the initial *health condition* has been observed and analysed by at least one *healthcare professional*, it becomes a professionally *observed condition*. The *healthcare professional* can also conclude one or several *potential conditions*. A *potential condition* is a *health condition* that either

- exists though is not yet observed, or
- does not yet exist but for some reason is assessed as possible to develop.

When a *health condition* is suspected but not yet observed it is a *considered condition* (a type of *potential condition*). If the *considered condition* is not observed after relevant investigations, it may be designated an *excluded condition* by a *healthcare professional.*

The initial *health condition* is then the basis for a *healthcare needs assessment* identifying the *needed healthcare activity* (healthcare investigations and/or treatments). During the successive steps of the process, aspects of the *health state* are re-observed and interpreted and so new *observed conditions* develop

During the process, especially after investigations but also after treatments, a number of *health conditions* are observed by *healthcare professionals* and also by the *subject of care*. *Healthcare professionals* analyse, assess and draw conclusions based on the *observed conditions*. Certain such professional conclusions/opinions change the observed conditions to become *professionally assessed conditions*

The types of conclusions/opinions by a *healthcare professional* that define a *professionally assessed condition* are:

- the reason for;
- the prognosis for; and/or

- the impact on the health state or severity of the *health condition*.

The desired possible outcome of a *healthcare/clinical process* is a *target condition*. The achievement of this *potential condition* can represent the *healthcare objective* of a *care plan*. The actual outcome of healthcare activity elements and *healthcare / clinical processes* are *resultant conditions*.

Foreseen consequences of *adverse events* can be described as *risk conditions,* which are another type of potential condition.

In summary, the types of *health conditions* in a *clinical process* are:

- *observed conditions* (observed by the *subject of care, healthcare professionals* and/or other *healthcare actors*);
- *considered conditions* (described by the *subject of care* and/or by *healthcare professionals*);
- *excluded condition* (designated by a *healthcare professional*);
- *professionally assessed conditions* (observed and assessed by *healthcare professionals*);
- *prognostic conditions* (described by *healthcare professionals*);
- *risk conditions* (described by *healthcare professionals*);
- *resultant condition* (described by *healthcare professionals* or *subject of care*);
- *target conditions* (described by the *subject of care* and/or by *healthcare professionals*).

A.6.1.4 Activities and activity management used to transform the health state of a subject of care

The transformation of the *health state* is provided by *healthcare activity elements, being parts of the more complex healthcare activities*. The activity elements in the *healthcare/clinical process* have two main aims:

- to clarify the health problem (by healthcare investigations); and
- to undertake action to influence the identified problems (by healthcare treatments).

Healthcare activity elements are regarded as direct when they are performed in interaction with the *health state* of the *subject of care*. In this International Standard the different aims for healthcare activities are regarded as elements of the activities. Direct healthcare activities are then considered to have two distinct elements – investigation and treatment.

Due to the nature of delivery, *healthcare activity elements* for investigation and treatment will have different statuses during the *healthcare/clinical process*; the illustrative statuses are drawn from EN 12967-1:2011.

During their performance they will have a status of 'ongoing'/in 'action'. Before and after this performance stage, other statuses are the result of 'indirect' *healthcare activity elements*; the main kinds of these are to *perceive/observe, assess, plan* and *evaluate*.

The main elements of *healthcare activities* are:

Perceive/Observe: To observe is to recognize a phenomenon and could be done by a device or a person. To perceive is when a person descriptively interprets the observation by human senses. The most important example of observing in the process model is to *observe* an aspect of a *health state* as a *health condition.*

Assess: To assess is to form an opinion concerning the relevance of the *observed conditions*. Examples of assessments from the healthcare/clinical process model (and resulting in a *professionally assessed condition*) are to

- assess the cause,
- predict the course of the health state and

- identify the severity of an *observed health condition*.

Additionally,

- assessment of the need for *healthcare investigations* or *healthcare treatments* (*healthcare needs assessment*) will take place to inform the *care planning* and
- assessment of the effect on the *health state* and comparing it to a *target condition*.

Plan: Both observations and assessments are kinds of preparation for investigating and/or therapeutic activity elements. The *care plan* is the centre around which the *healthcare/clinical process* is delivered and covers all stages of the activities' life cycles.

Take action: In the process model to take action is to perform/execute the investigations and/or the treatments that are set out in the *care plan.*

A.6.2 Steps in the generic healthcare/clinical process model

A.6.2.1 Perceive a demand for care and create, or merge into, a health concern

A person who perceives some symptoms, discomfort or other worry that they believe to be a *health issue* that a *healthcare organization* can manage decides whether to get in touch with a *healthcare provider*. This approach to the provider is a *demand for care*, (more specifically, a *demand for initial contact*). The reason for the demand is a *health issue,* often specified as a *health condition* and/or a *health problem* (a health condition considered to be a problem).

A *healthcare professional* then accepts this approach from the subject of care as a *demand for care* that will also include an initial assessment if a contact is required and subsequently undertaken.

A comprehensive *clinical process* may involve (and require) that several *healthcare providers* in different *healthcare organizations* cooperate, sometimes for long periods of time. Continuity of care for the *subject of care* requires that all information related to the specific *clinical process* is identified, labelled, tracked and made available to all *healthcare actors*. To achieve this, a concept for the gathered information regarding a comprehensive *clinical process* is needed – termed as a *health concern* for a *clinical process*. All information about *health conditions*, investigating and therapeutic activity elements, etc. that relate to the *clinical process* can then be traced, followed and coordinated by the *health concern*. This concept also makes it possible to fulfil a *continuity responsibility* (a '*continuity facilitator mandate*') for a *clinical process*.

The information that is included in one *health concern* for a *clinical process* is decided by the *healthcare professional* that documents the information. When coordination and management of *health issues/problems* are assessed to be beneficial to the *health state* of the *subject of care*, several *clinical processes* could be merged into the same *health concern*.

A.6.2.2 Assess the needs for healthcare investigations

The next step is to assess the needs for *healthcare activities*, aiming to identify *health conditions* (via *healthcare investigations*) that represent the *health state*, the *health need* and the *health problems*. The *healthcare needs assessment* is based on the *health need* and the *observed* and/or the *potential conditions* concluded by the *healthcare professionals*, who assume the responsibility (a *healthcare mandate*) for the decisions to propose activities to be added in the *care plan*.

A *healthcare commitment* from the *healthcare provider* to perform the *needed healthcare activity* - combined with an *informed consent* from the *subject of care* - is a kind of *healthcare mandate*.

A.6.2.3 Plan for healthcare investigations

If *needed healthcare investigations* are identified, those activities are planned and put into the *care plan*. The analysis of the *health state* is facilitated through *healthcare investigations* and further refining the identification of *health conditions*.

Following consultation/dialogue (commonly between one *healthcare professional* and the *subject of care*) about the assessment, a *care plan* including the proposed *healthcare investigations* is drawn up. The responsibilities for the coordination of these continuity aspects should be documented (as a *continuity facilitator mandate*).

A.6.2.4 Perform healthcare investigations

Performing *(taking action)* the planned *healthcare investigations* is the next process step. Certain activities may be performed/executed by the *subject of care* (*health self care activities),* though most of the activity elements will be performed by *healthcare professionals* in *healthcare provider activities*.

Each professional is usually responsible for the activity they perform and this is distinguished from the *continuity facilitator mandate,* which relates to the coordination and follow-up of all relevant activities in the *care plan*.

A.6.2.5 Assess if the identified health conditions motivate healthcare treatment

Healthcare professionals *perceive* and *analyse* the results of their investigating activities and draw conclusions (informed opinions) about the *resultant conditions*. This analysis concludes whether the *health condition* would normally require *healthcare treatments* or not; that is to say whether it fulfils criteria for the knowledge based medical indications.

A.6.2.6 Assess the needs for healthcare treatment

Based on the identified *resultant conditions after completed investigations* an extended *healthcare needs assessment* for performing *therapeutic activities elements* takes place. This takes all circumstances related to the *subject of care* into consideration thus providing a holistic view of the indications and benefits of healthcare treatment. This will be completed in consultation and dialogue with the *subject of care* and other *healthcare professionals.*

The assessment of needs for healthcare treatment is based upon the *health conditions/health problems* – usually expressed as a diagnosis at the conclusion of the *healthcare investigations*. Other circumstances related to the *health need* of the *subject of care* will also be considered.

The assessment activity may also include setting *healthcare goals* and *healthcare objectives* for the treatment proposed. These should be based upon the need for better health (the *health need*) and can be formulated as one or several *target conditions*.

The *health conditions* identified can be assessed as not requiring therapeutic activities and following consultation with the *subject of care*, a renewed *assessment of healthcare needs* for further *healthcare investigations* is performed. If there is nothing further to add, then the process is finished.

A.6.2.7 Care planning for healthcare treatment

If treatment is assessed as needed, the next step will be to add or update these activity elements in the current *care plan*.

A.6.2.8 Perform healthcare treatment

The next step is to perform the planned *healthcare treatments*. Some treatments are undertaken by the *subject of care* (*health self care activities*) but most of the activities are undertaken by *healthcare professionals*. The *continuity facilitator mandate* is reviewed every time the *care plan* is changed.

A.6.2.9 Assess the effect on the health state – evaluation

The results of a single or package of *healthcare treatment elements* are the transformation of the inputs into the outputs (the value added to the *health state*). These values are described as several *health conditions* during the treatment. After completion of all activity elements in the *care plan,* the clinical

process outcome (its' effect on the *health state*) is observed, analysed and described as one or more *resultant conditions*.

The *resultant conditions* are compared to the *target condition* and/or to earlier observations of the same type of *health condition*. The *health need* can be regarded as satisfied if the *target condition* is achieved. If all *healthcare professionals* (and where appropriate the *subject of care*) involved agree that there is no need for further *healthcare activities*, the *clinical process can* be concluded.

A.7 The enterprise/information areas models and interrelations to groups of concepts

A *healthcare/clinical process* is dependent upon several phenomena within and around the core process.

Perspectives of the healthcare operations such as administration, resource logistics, information and financial management are represented by concepts not included in the core process. These can be subdivided in different areas or categories that relate to the core process.

Process- and resource management are the main components. Information and financial management are other constituent components intrinsic to the delivery of healthcare.

The links across the information areas and the normative clauses 5 – 12 are shown in Figure A.5.

The main components related to the *clinical process* are shown as horizontal bars. The supporting components to the sides represent information management (including information security) and finance management.

The areas are grouped around the *clinical process*. Below the clinical process are the supporting resources supplied to enable the delivery of services that are made accessible for the *healthcare activities* in the *clinical process*.

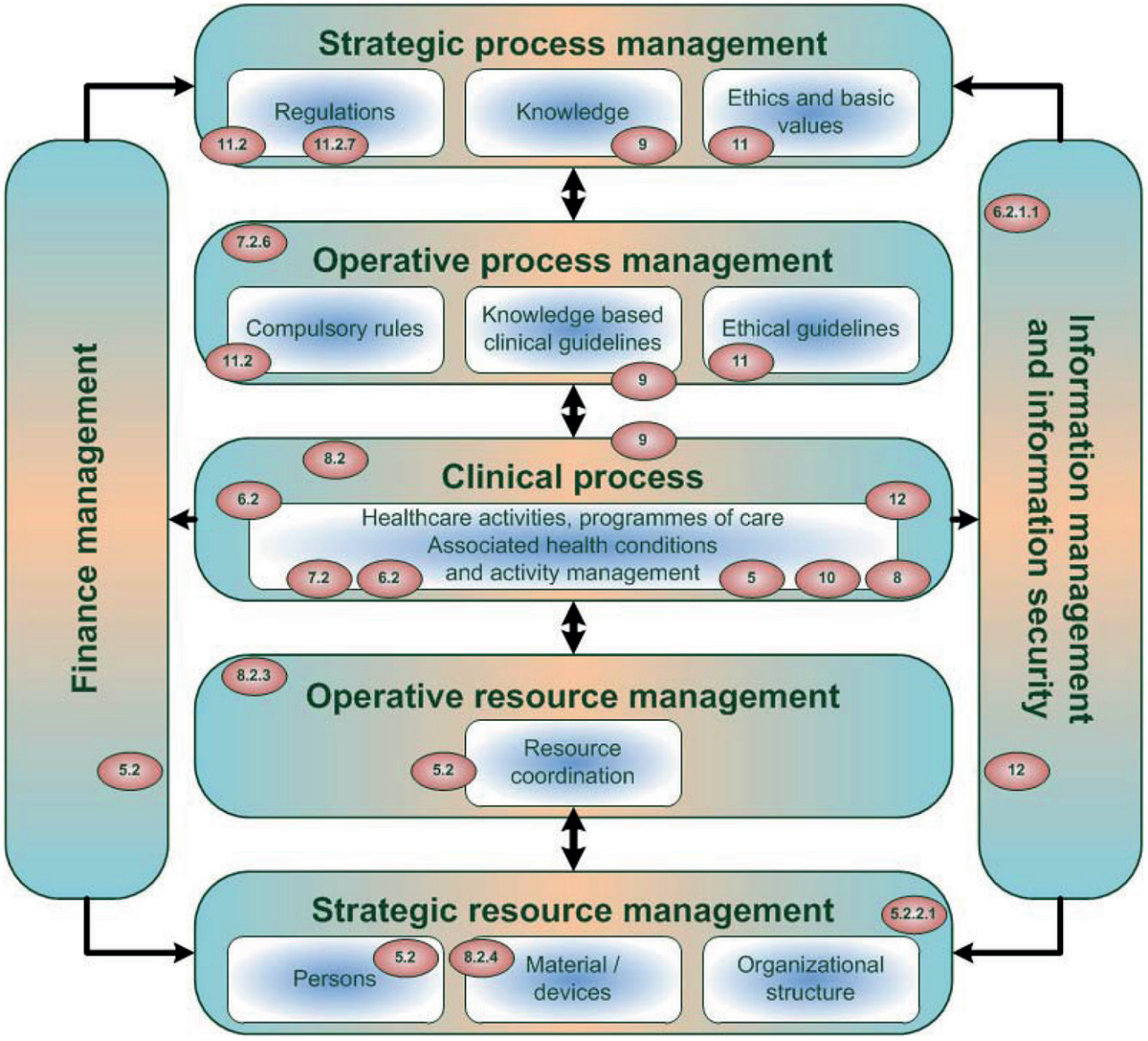

Figure A.5 — Organizational information areas with references to normative clauses

The resource area is subdivided into strategic and operational and includes personnel, material/devices and organizational structures.

Strategic and operative process management are shown above the *clinical process*. The strategic process management is subdivided into regulations (based upon laws and directives), knowledge base (scientific and best practice) and ethical and basic values.

Operative process management has direct interaction with the *clinical process*. This is subdivided into knowledge based recommendations as guidelines and protocols possibly supported by *standardized/core care plans*, directives based upon regulations and compulsory rules and ethical guidelines for prioritization of care.

Finance management gathers both production and productivity related information from the *clinical process* and feeds that to the strategic resource and strategic process management areas (the costs for resources consumed by the activities and the cost of chosen recommendations and input to priority strategies).

The documents concerning the *healthcare activities* and the observations of the health state that are produced in the *clinical process* is included in the core process. The management of that documented

information is dealt within the information management area. The documentation about the results feed the strategic management (through information management) with additional knowledge that is useful for reviewing and improving operative process management.

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