

Health informatics — System of concepts to support continuity of care

Informatique de la santé — Système de concepts en appui de la continuité des soins

Medizinische Informatik — System von Konzepten zur Unterstützung der ununterbrochenen Pflege

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0. Introduction (Informative)

0.1 General

The purpose of this 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 with semantic interoperability 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 standard is based on the clinical perspective with the clinical process in focus and defines its component concepts and their descriptive terms, regarding all types of healthcare and especially considering patient-centred continuity of care. This standard will establish a common conceptual framework across national, cultural and professional barriers.

0.2 Aims for this standard

The general aim for this 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. This further enables the use of clinical 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 standard. To be able to represent both clinical content and clinical context, this standard is based upon the clinical perspective and has focus on 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 concepts relations for the clinical, management and resource aspects of healthcare services.

In practice this 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 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 emphasising 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 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 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 standard should also be applicable for social care.

0.5 Target groups for this 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 may 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 should 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 below.

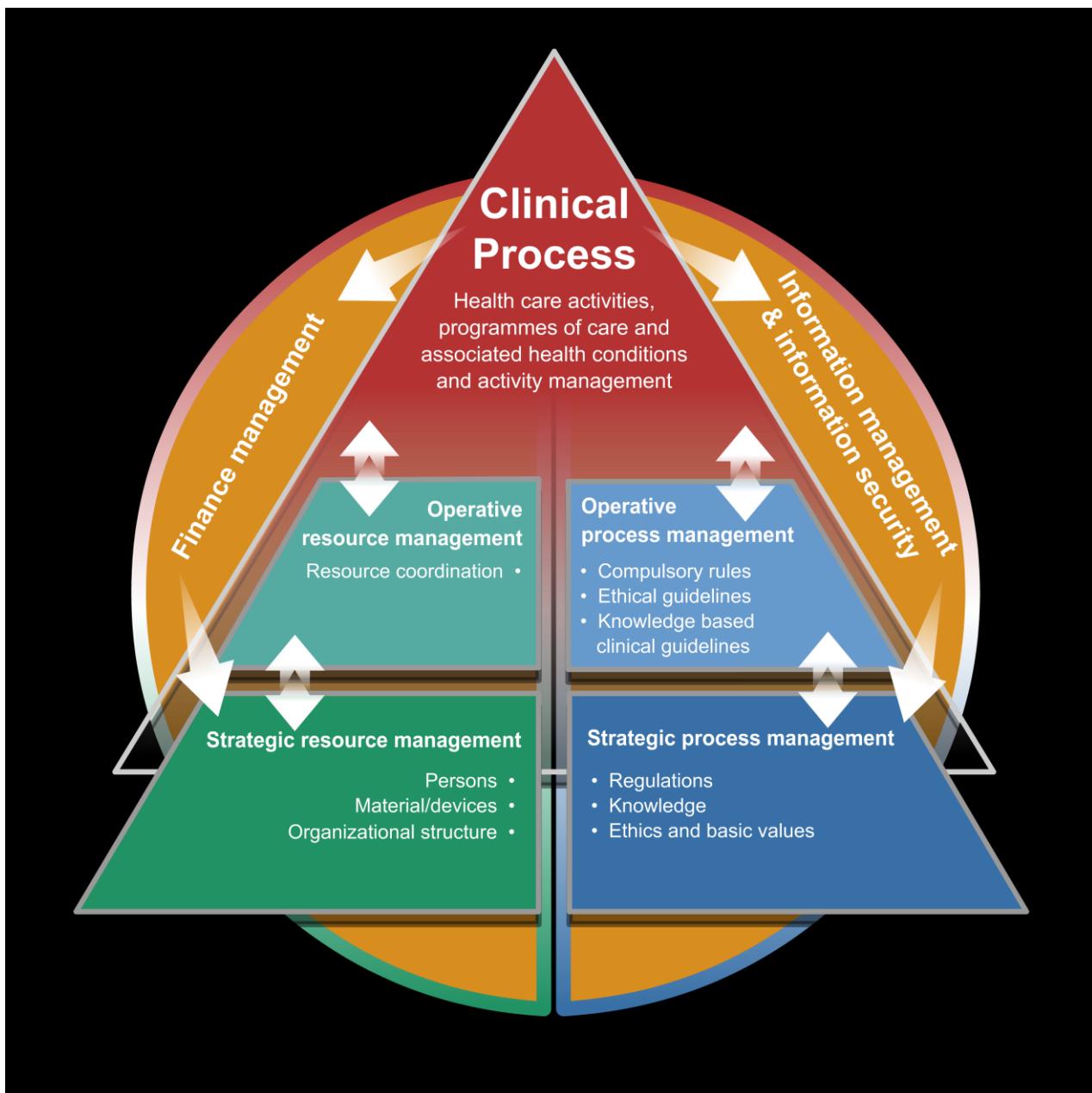


Figure 1 — Architecture of the concept areas (Informative)

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 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. Italic characters are used in the headings of those concepts that are purely abstract constructs and therefore supported only through their specializations.

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 compliant with ISO/TR 24156:2008. For each one of the concepts described in Clauses 5 to 12, a partial view of the general and comprehensive diagram is provided, showing only its direct relationships with other concepts belonging to the relevant aspect of the system of concepts.

Diagrams providing partial views of the system of concepts are also shown at the beginning of Clauses 5 to 12. These diagrams are focused on the topic addressed in the corresponding clause. For clarity of reading, concepts shown in white with a solid border are defined in the clause to which the diagram belongs.

Concepts defined in other clauses of the standard are shown in grey with a solid border while concepts not defined in this standard are shown in grey with a dashed border. While all relationships are included for the concepts shown in white, the relationships between concepts shown in grey are not included in the diagrams.

The purpose of using concept models in this standard is to highlight the relationships between concepts. Their attributes, which do not belong to the field of concept modeling, are not addressed in this standard. This means that additional attributes may be felt useful or necessary in the course of implementation, without conformance with the current standard being at stake.

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 standard. To be able to represent both clinical content and clinical context, this 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 standard covers the concept definitions needed whenever structured information in healthcare is specified as a requirement. This 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.

The performance of any specific healthcare and clinical processes, healthcare research processes and healthcare educational processes are not covered in this standard.

2. Normative references

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

EN-ISO 9000:2005, Quality management systems – Fundamentals and vocabulary

3. Terms and definitions

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

3.1 appointment

arrangement to meet someone at a particular time and place

3.2 clinical data

data regarding the healthcare or clinical process

3.3 clinical information

information about a *person*, relevant to his or her healthcare

[ISO 13606-1:2008]

3.4 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.

[ISO 12967-1:2009]

3.5 concept

unit of knowledge created by a unique combination of characteristics

[ISO 1087-1:2000]

3.6 continuity of care

efficient, effective, ethical care delivered through interaction integration, co-ordination and sharing of information between different healthcare actors over time

3.7 data

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

[ISO/IEC 2382-1:1993]

NOTE 1 to entry: Data is defined without any context in such a way that by itself one cannot tell its correct meaning.

3.8 data repository

an identifiable data storage facility

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

3.9 deprecated term

term rejected by an authoritative body

[ISO 1087-1:2000]

3.10 electronic health record

repository of information regarding the health of a subject of care, in computer processable form

[ISO 13606-2:2008]

3.11 entity

concrete or abstract thing of interest

NOTE 1 This includes associations among things

Modified from [ISO 18308:2011]

3.12 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 healthcare framework.

[Adapted from ISO/TR 18307:2001]

3.13 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 may be regarded as information once its meaning is revealed.

3.14 information model

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

[ISO 10303-1:1994]

3.15 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 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.
[EN ISO 14971:2009]

NOTE 4 to entry: The definition is recursive as the term appears in the sixth bullet point, which means that it does not comply with terminological rules according to ISO 703. The meaning is simply, that a device used for service of a medical device is included in the definition.

3.16 organization

unique framework of authority within which a person or persons act, or are designated to act towards some purpose

[ISO/IEC 6523-1:1998]

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.

3.17 organizational pattern

relationships between the various parts of an *organization*

3.18 organization role

role of an *organization*

3.19 party

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

[ISO 8459:2009]

3.20 person

human being regarded as an individual

[Oxford English Dictionary]

3.21 person role

role of a *person*

3.22 process

set of interrelated or interacting activities which transforms inputs into outputs

NOTE 1 to entry: Inputs to a process are generally outputs of other processes. In that sense, because their output can be used as an input to another process, activities may be considered as resources in a process.

[ISO 9000:2005]

3.23 process model

representation of a process

3.24 quality in healthcare

degree to which healthcare fulfils requirements related to defined quality characteristics

NOTE 1 to entry: Quality is defined in ISO 9000:2005, 3.11 as the 'degree to which a set of inherent characteristics fulfil requirements'

3.25 quality management

coordinated activities to direct and control an *organization* with regard to quality

NOTE 1 to entry: Direction and control with regard to quality generally includes establishment of the quality policy and quality objectives, quality planning, quality control, quality assurance and quality improvement.

[ISO 9000:2005, 3.2.8]

3.26 quality assurance

part of *quality management* focused on providing confidence that quality requirements will be fulfilled

[ISO 9000:2005, 3.2.11]

3.27 quality control

part of *quality management* focused on fulfilling quality requirements

[ISO 9000:2005, 3.2.10]

3.28 resource

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

NOTE 1 to entry: Resources may include 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 may be reusable, renewable or consumable.

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

[ISO/IEC 15288:2008]

3.29 risk

combination of the probability of an event and its consequences

[ISO Guide 73]

3.30 role

function or position

[ISO/HL7 21731:2006]

3.31 system of concepts

DEPRECATED: concept system

set of concepts structured according to the relations among them

[ISO 1087-1:2000]

3.32 unintended event

phenomenon that is not part of the normal course of a *process* but may 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 may prove negative or positive in comparison to the desired process outcome.

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

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. Actors in continuity of care

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 please refer to clause 0.5 of this document.

NOTE For the guidelines for using UML diagrams please see PD ISO/TR 24156:2008 *Guidelines for using UML notation in terminology work*.

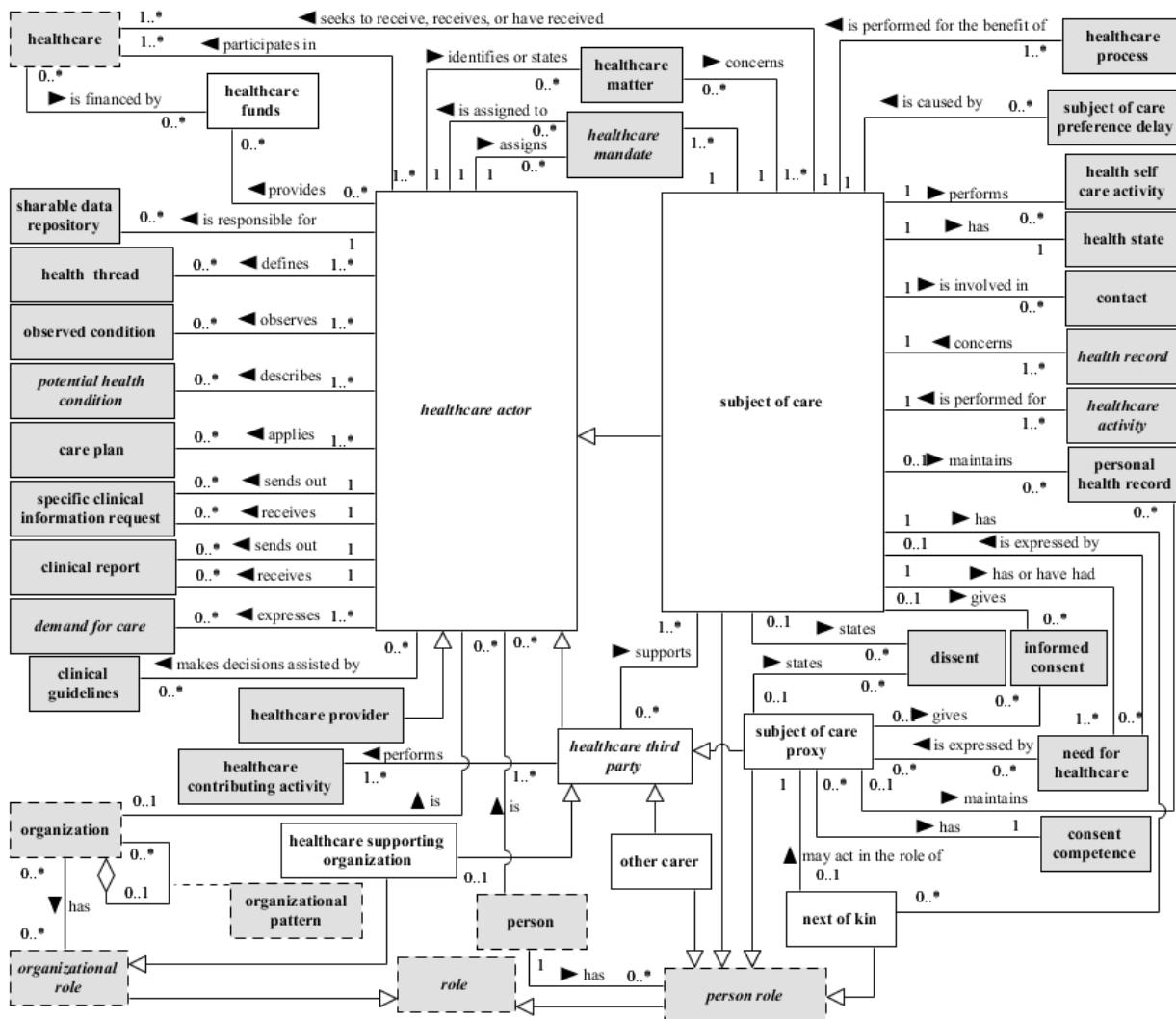


Figure 2 — Comprehensive UML diagram of actors in Continuity of Care, part 1

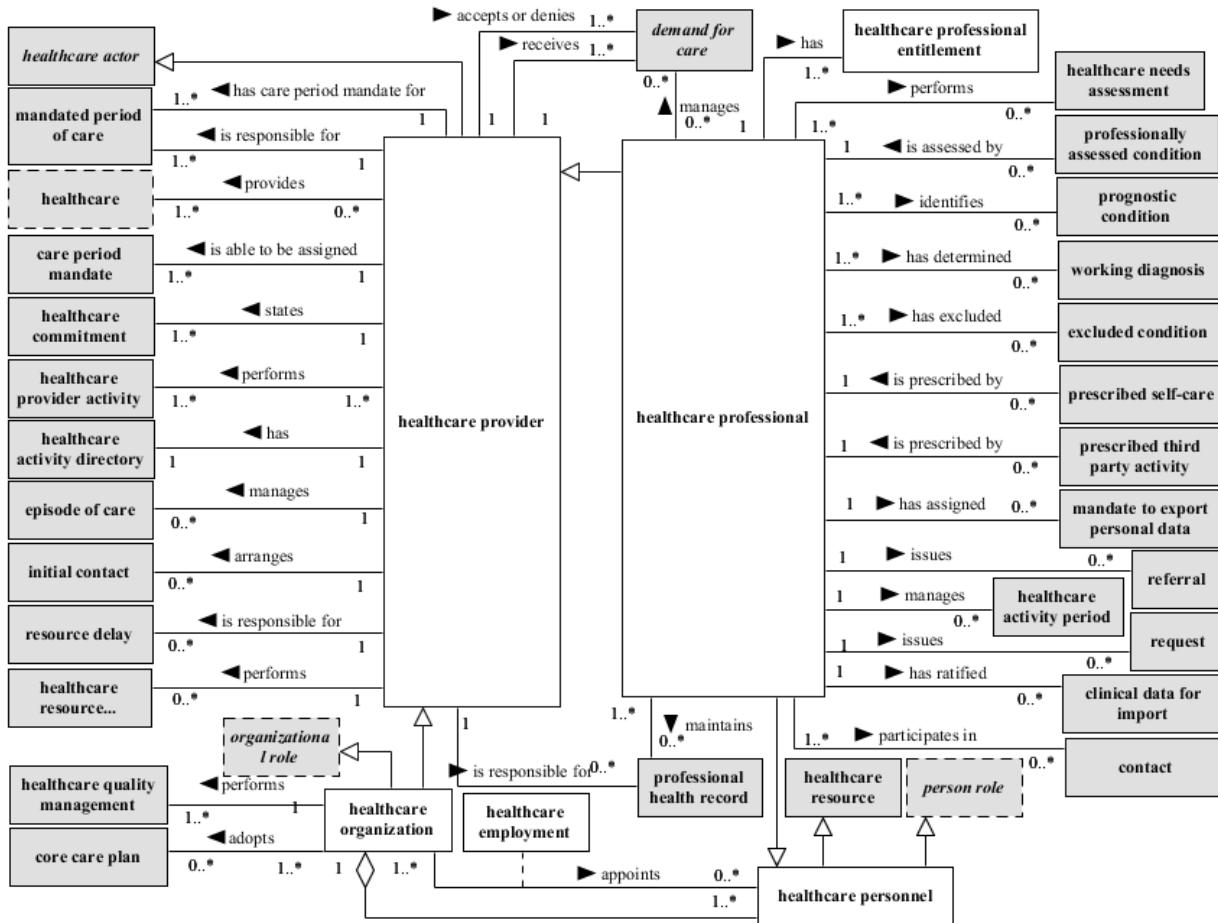


Figure 3 — Comprehensive UML diagram of actors in Continuity of Care, part 2

5.2 Healthcare actor

Term:	<i>healthcare actor</i>					
Deprecated term:	healthcare party					
Definition: organization or person participating in <i>healthcare</i>						
NOTE 1 The involvement of the <i>healthcare actor</i> 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 <i>healthcare actors</i> , as well as organizations responsible for healthcare delivery.						
According to this definition, <i>healthcare actor</i> is a superordinate concept to <i>healthcare provider</i> , (i.e. <i>healthcare organization</i> and <i>healthcare professional</i>), healthcare third party and also subject of care.						
NOTE 3 In EN 13940-1:2007 healthcare party was the preferred term for this concept.						
Specialization of	Generalization of					
	healthcare provider					
	subject of care					
	healthcare third party					
Association from	Association name	Association to				
1..*	healthcare actor	participates in	1..* healthcare			
1	healthcare actor	identifies or states	0..* health healthcare matter			
1	healthcare actor	defines	0..* health thread			
1	healthcare actor	makes decisions assisted by	0..* clinical guidelines			
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..* specific clinical information request			
1	healthcare actor	receives	0..* specific clinical 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	observes	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	organisation	is	0..* healthcare actor			
0..*	certificate related to healthcare matter	is issued by	1..* healthcare actor			

A model showing the associations of this concept is shown in Figure 47.

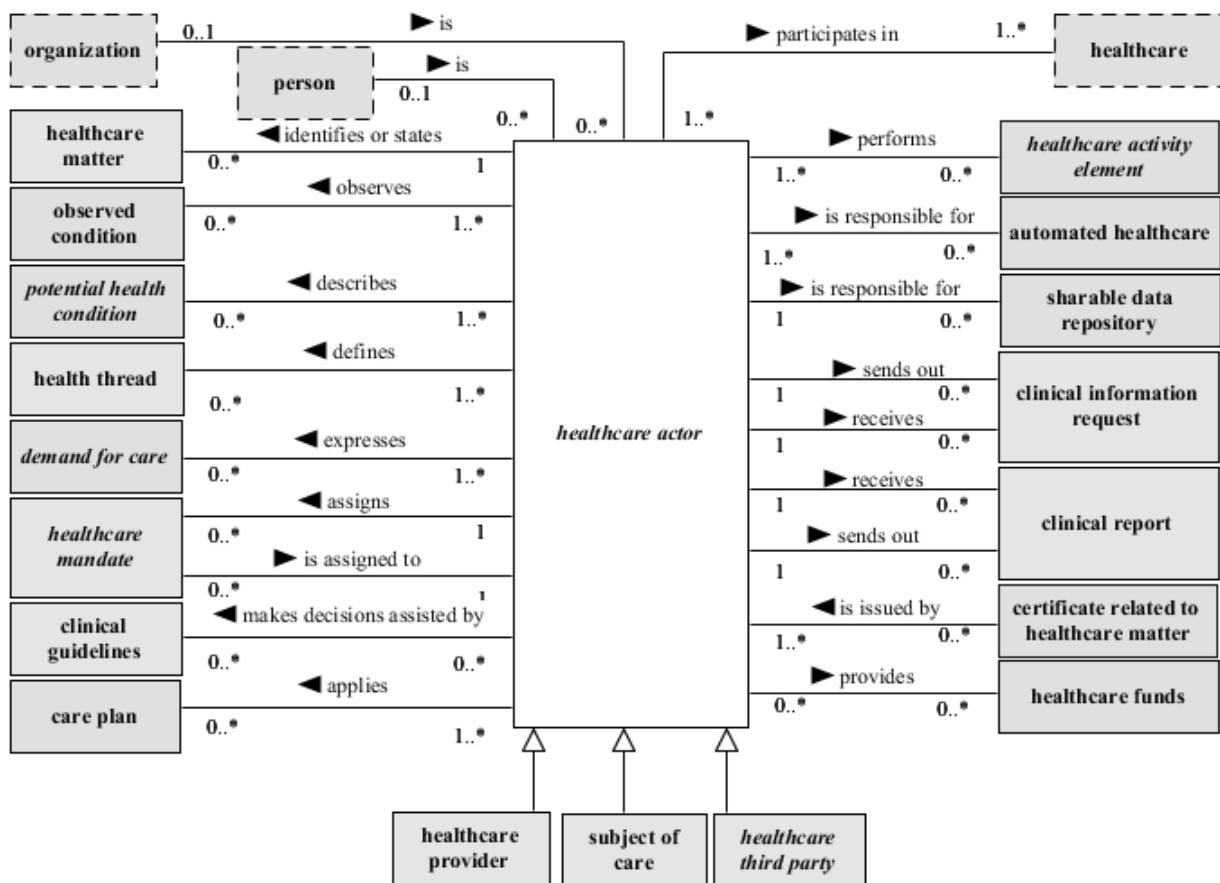


Figure 4 — Healthcare actor (UML representation)

5.2.1 Subject of care

Term:	<i>subject of care</i>		
Synonyms:	subject of healthcare, patient, client, service user		
Definition:	<i>healthcare actor having person role seeking to receive, receiving, or having received healthcare</i>		
<p>NOTE A foetus, when receiving <i>healthcare</i>, is to be considered as a subject of care.</p> <p>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.</p>			
Specialization of	Generalization of		
healthcare actor			
person role			
Association from	Association name	Association to	
1 subject of care	has	1	health state
1 subject of care	has or have had	0..*	health need
1 subject of care	maintains	0..*	personal health record
1 subject of care	is involved in	0..*	contact
1 subject of care	performs	0..*	self-care activity
1 subject of care	has	0..*	next of kin
1 subject of care	has		
1 subject of care	has		
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 preference delay	is caused by	1	subject of care
1..* healthcare process	is performed in benefit of	1	subject of care
1..* healthcare activity	is performed for	1	subject of care
1..* health issue	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

A model showing the associations of this concept is shown in Figure 5.

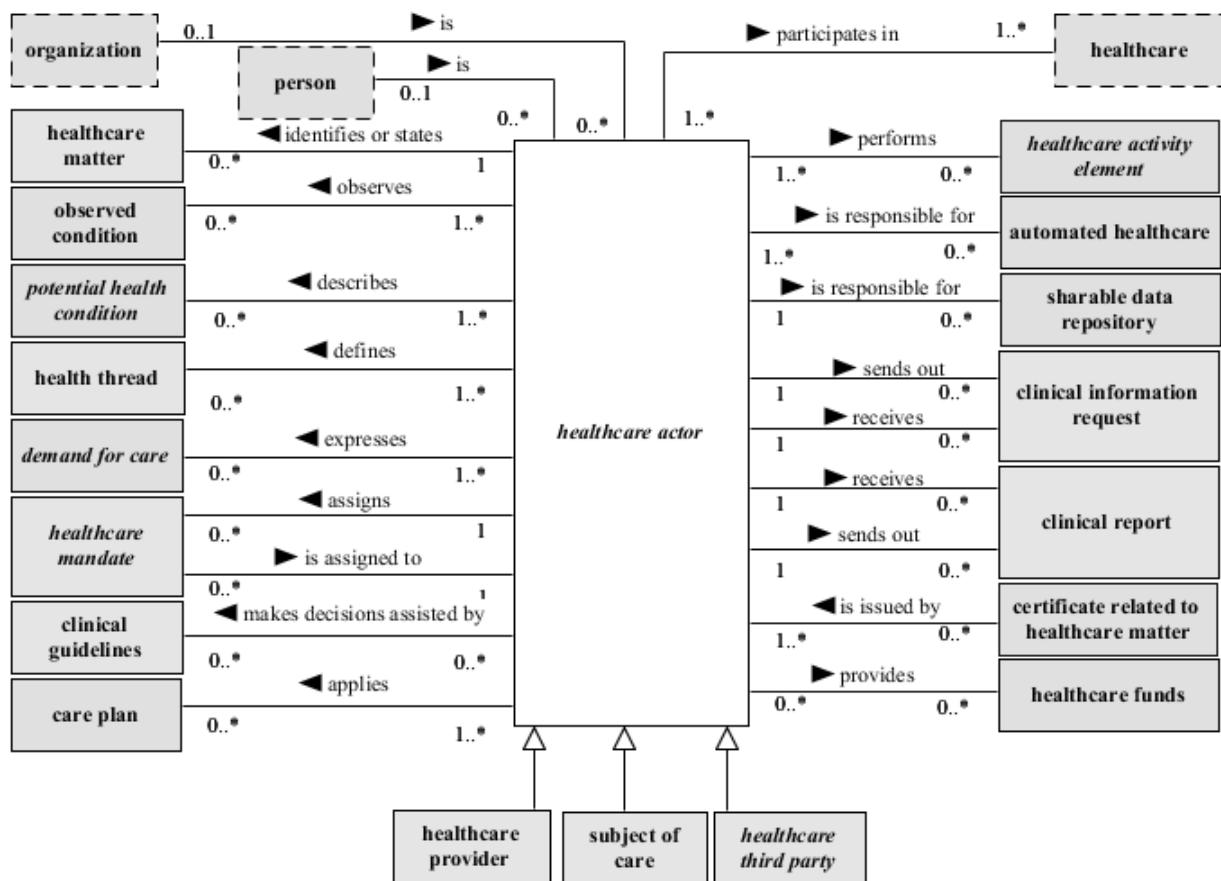


Figure 5 — Subject of care (UML representation)

5.2.2 Healthcare provider

Term: <i>healthcare provider</i>		
Synonym: care provider, health provider, health care provider, health service provider		
Definition: <i>healthcare actor</i> that is able to be assigned one or more <i>care period mandates</i>		
NOTE 1 The personnel of a <i>healthcare organization</i> that is a <i>healthcare provider</i> may include both <i>healthcare professionals</i> and others which participate in the provision of healthcare.		
NOTE 2 This International Standard includes only two specializations of <i>healthcare provider</i> . This is not meant to exclude the possibility of other specializations. In jurisdictions where other kinds of <i>healthcare actors</i> are included in the concept of <i>healthcare provider</i> , 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 <i>healthcare providers</i> ; for the purpose of this International Standard they are considered as <i>healthcare third parties</i> .		
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

A model showing the associations of this concept is shown in Figure 6

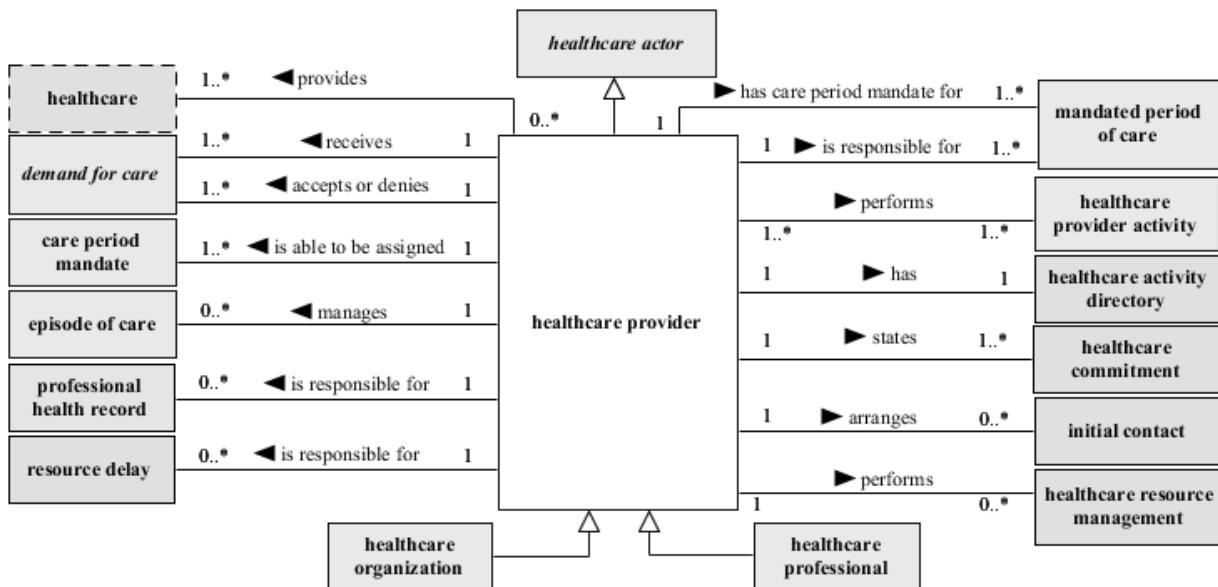


Figure 6 — Healthcare provider (UML representation)

5.2.2.1. Healthcare organization

Term: <i>healthcare organization</i>		
Synonym: care organization, healthcare organisation, care organisation		
Definition: <i>healthcare provider having an organization role</i>		
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, i.e. other lower level organizations. A <i>healthcare organization</i> represents the role any such organization plays when it is involved in the direct provision of <i>healthcare activities</i> .		
NOTE 2 Effectively, a <i>healthcare organization</i> 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 e.g. a specific type of <i>clinical process</i> with participants from different departments is also a kind of <i>healthcare organization</i> .		
NOTE 3 A free-standing self-employed solo practising <i>healthcare professional</i> shall be considered as the only member of his/her own <i>healthcare organization</i> .		
NOTE 4 Organizations may have a number of different roles. When an organization acts in a role where its <i>healthcare personnel</i> participate in the direct provision of healthcare, it is called a <i>healthcare organization</i> .		
EXAMPLES A care team, a group practice, a hospital, a hospital department, a hospital care unit, self-employed GP		
Specialization of	Generalization of	
healthcare provider		
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

A model showing the associations of this concept is shown in Figure 7.

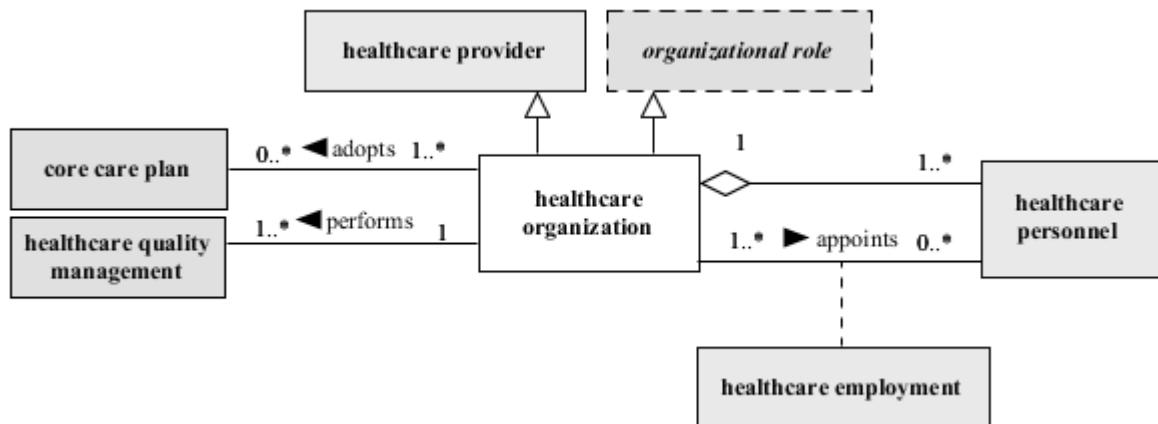


Figure 7 — Healthcare organization (UML representation)

5.2.3 Healthcare personnel

Term:	<i>healthcare personnel</i>	
Synonyms:	care personnel, individual provider	
Definition: <i>healthcare actor having a person role in a healthcare organization</i>		
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.		
Specialization of	Generalization of	
person role	healthcare professional	
healthcare resource		
Component of	Aggregation of	
0..* healthcare organization		
Association from	Association name	Association to
1..* healthcare organization	appoints	0..* healthcare personnel

A model showing the associations of this concept is shown in Figure 8.

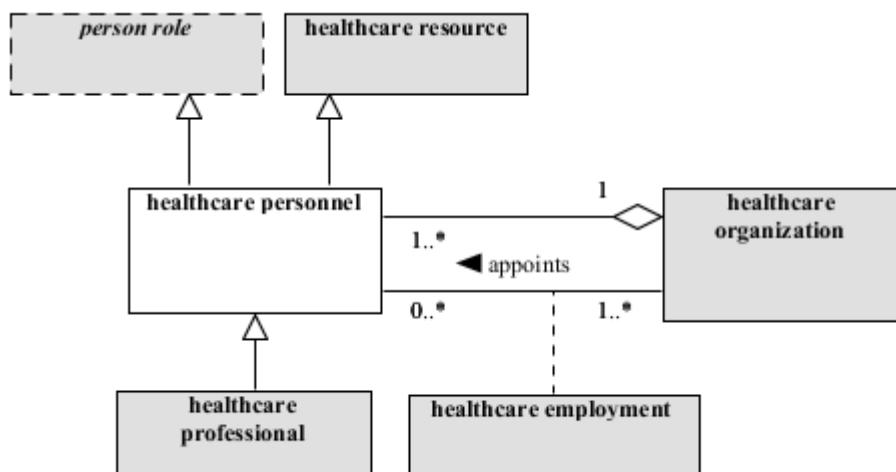


Figure 8 — Healthcare personnel (UML representation)

5.2.3.1. Healthcare employment

Term:	<i>healthcare employment</i>	
Synonym:	care employment	
Definition: contractual framework between a <i>healthcare personnel</i> and a <i>healthcare organization</i> describing the roles and responsibilities assigned to that <i>healthcare personnel</i>		
Association concept	Links	
1 healthcare employment	1 healthcare personnel	1 healthcare organization

A model showing the associations of this concept is shown in Figure 9.

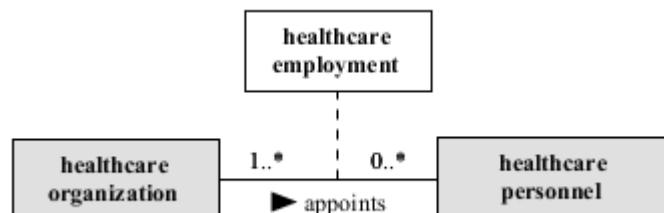


Figure 9 — Healthcare employment (UML representation)

5.2.3.2. Healthcare professional

Term: <i>healthcare professional</i>			
Synonym: care professional			
Definition: <i>healthcare personnel having a healthcare professional entitlement recognized in a given jurisdiction</i>			
EXAMPLES GP, medical consultant, therapist, dentist, nurse, radiographer etc.			
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..*	clinical data for import
1 healthcare professional	has assigned	0..*	mandate to export personal data
0..* healthcare professional	manages	0..*	demand for care
1..* healthcare professional	identifies	0..*	prognostic condition
1 healthcare professional	has confirmed	0..*	working diagnosis
1 healthcare professional	has excluded	0..*	excluded condition
0..* professionally assessed condition	is assessed by	1	healthcare professional
0..* prescribed self-care	is prescribed by	1	healthcare professional
0..* prescribed contributing care	is prescribed by	1	healthcare professional
0..* healthcare professional	performs	0..*	healthcare needs assessment

A model showing the associations of this concept is shown in Figure 10.

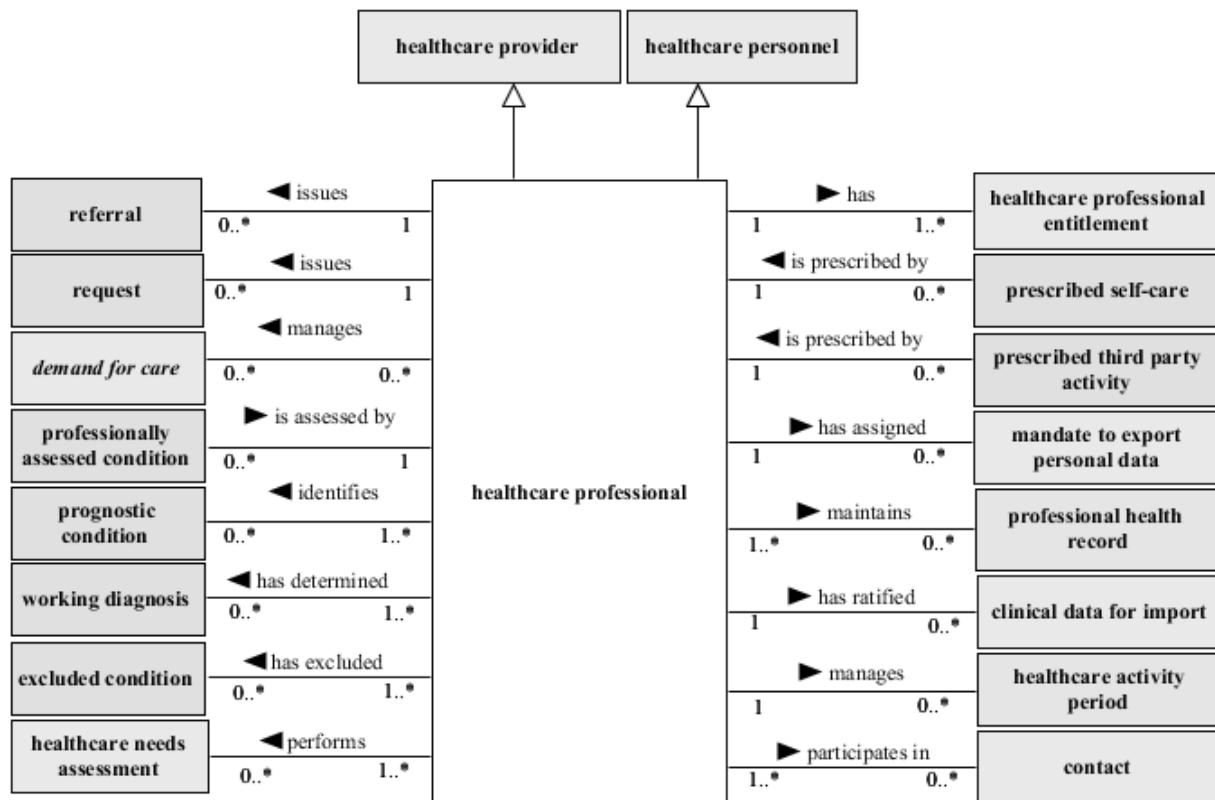


Figure 10 — Healthcare professional (UML representation)

5.2.3.3. Healthcare professional entitlement

Term: <i>healthcare professional entitlement</i>		
Synonym: care professional entitlement		
Definition: registered authorization given to a <i>person</i> in order to allow the <i>person</i> 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 <i>healthcare professional</i> forms the foundation for his/her official duties and rights.		
EXAMPLES Diploma, professional registration (e.g. registered nurse).		
Association from	Association name	Association to
1 healthcare professional	has	1..* healthcare professional entitlement

A model showing the associations of this concept is shown in Figure 11.

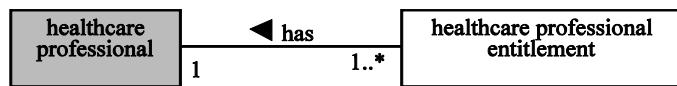


Figure 11 — Healthcare professional entitlement (UML representation)

5.2.4 Healthcare third party

Term: <i>healthcare third party</i>		
Synonym: care third party		
Definition: <i>healthcare actor other than a healthcare provider or the subject of care</i>		
NOTE 1 According to this definition, a relative (family member), any actor responsible for social support, or for the funding, payment, or reimbursement of healthcare provision are <i>healthcare third parties</i> .		
NOTE 2 <i>Healthcare third party</i> is an abstract superordinate generic concept which is only fully supported through the use of one of its subordinate specific concepts.		
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

A model showing the associations of this concept is shown in Figure 12.

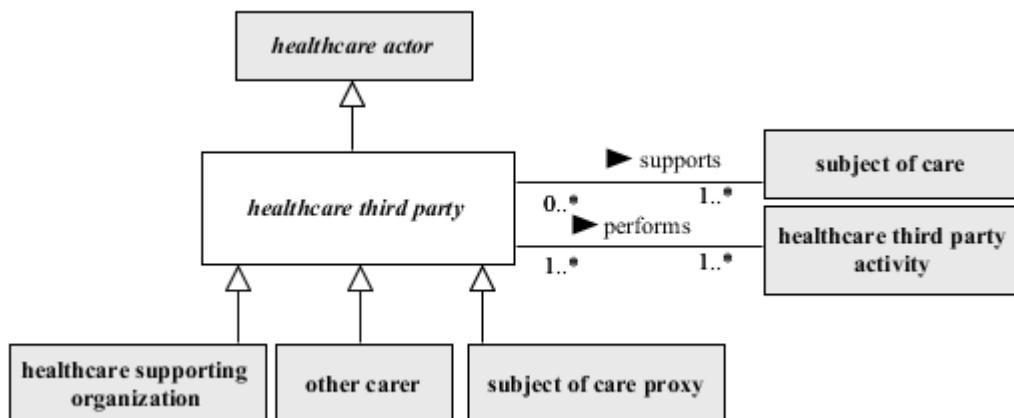


Figure 12 — Healthcare third party (UML representation)

5.2.4.1. Other carer

Term:	<i>other carer</i>
Synonym:	informal carer
Definition:	<i>healthcare third party having person role</i>
EXAMPLES	A relative (family member), a neighbour.
Specialization of	Generalization of
healthcare third party	
person role	

A model showing the associations of this concept is shown in Figure 13.

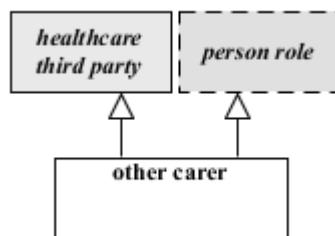


Figure 13 — Other carer (UML representation)

5.2.4.2. Healthcare supporting organization

Term: <i>healthcare supporting organization</i>
Synonym: care supporting organization
Definition: <i>healthcare third party having organizational role</i>
EXAMPLES Voluntary aid organization, a homecare service organization, a health insurance fund, the operator of a telemedicine system, family.
Specialization of
healthcare third party
health organization role
Generalization of

A model showing the associations of this concept is shown in Figure 14.

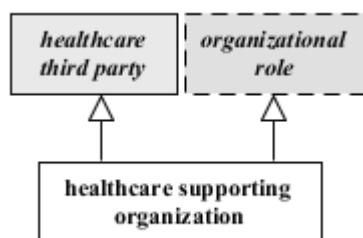


Figure 14 — Healthcare supporting organization (UML representation)

5.2.5 Next of kin

Term: <i>next of kin</i>	
Definition: person having a <i>person role</i> being either the closest living relative of the <i>subject of care</i> or identified as the person they have the closest relationship with	
NOTE If the <i>next of kin</i> has <i>consent competence</i> , the <i>next of kin</i> may also act in the role of <i>subject of care proxy</i> when required.	
Specialization of person role	Generalization of
Association from	Association name
1 subject of care	has
0..1 next of kin	may act in the role of
Association to	
	0..* next of kin
	1 subject of care proxy

A model showing the associations of this concept is shown in Figure 15.

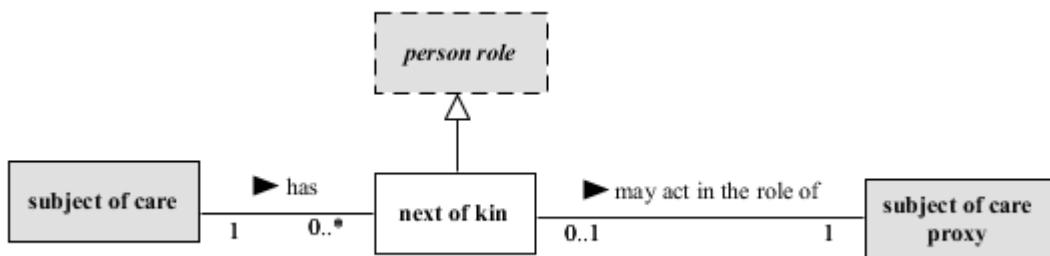


Figure 15 — Next of kin (UML representation)

5.2.6 Subject of care proxy

Term:	<i>subject of care proxy</i>		
Definition: <i>healthcare actor having person role with the right to take decisions on behalf of the subject of care</i>			
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..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	
0..1 next of kin	may act in the role of	1 subject of care proxy	

A model showing the associations of this concept is shown in Figure 16.

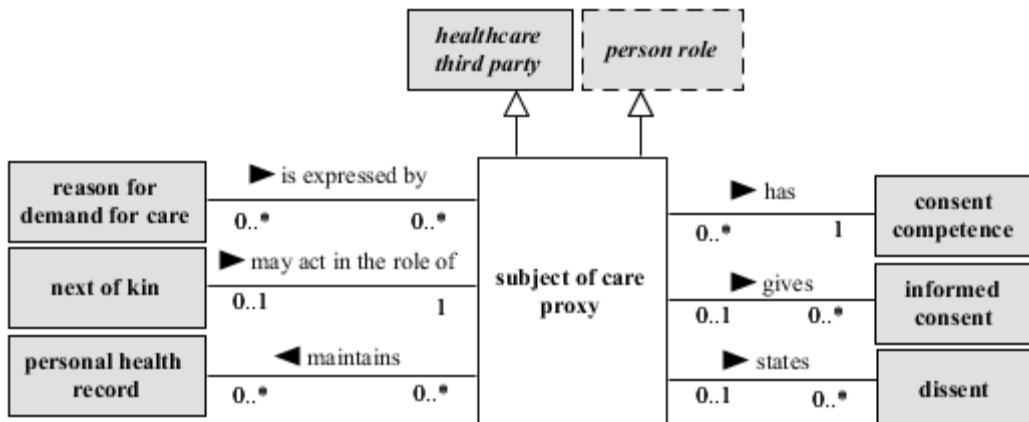


Figure 16 — Subject of care proxy (UML representation)

5.2.6.1. Healthcare funds

Term:	<i>healthcare funds</i>	
Synonym:	care funds	
Definition: funds provided for healthcare delivery		
NOTE Funds may be provided by e.g. 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.		
Association from	Association name	Association to
0..* healthcare	is financed by	0..* healthcare funds
0..* healthcare actor	provides	0..* healthcare funds

A model showing the associations of this concept is shown in Figure 17.

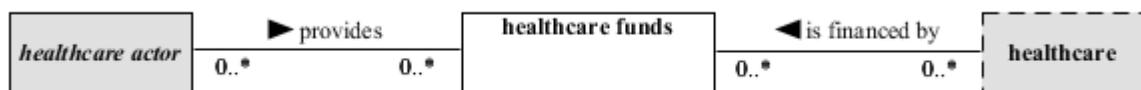


Figure 17 — Healthcare funds (UML representation)

6. Health issues and their management

6.1 General

A model showing the associations between concepts related to *health issues* and the other concepts defined in this International Standard is shown in Figures 18 and 19.

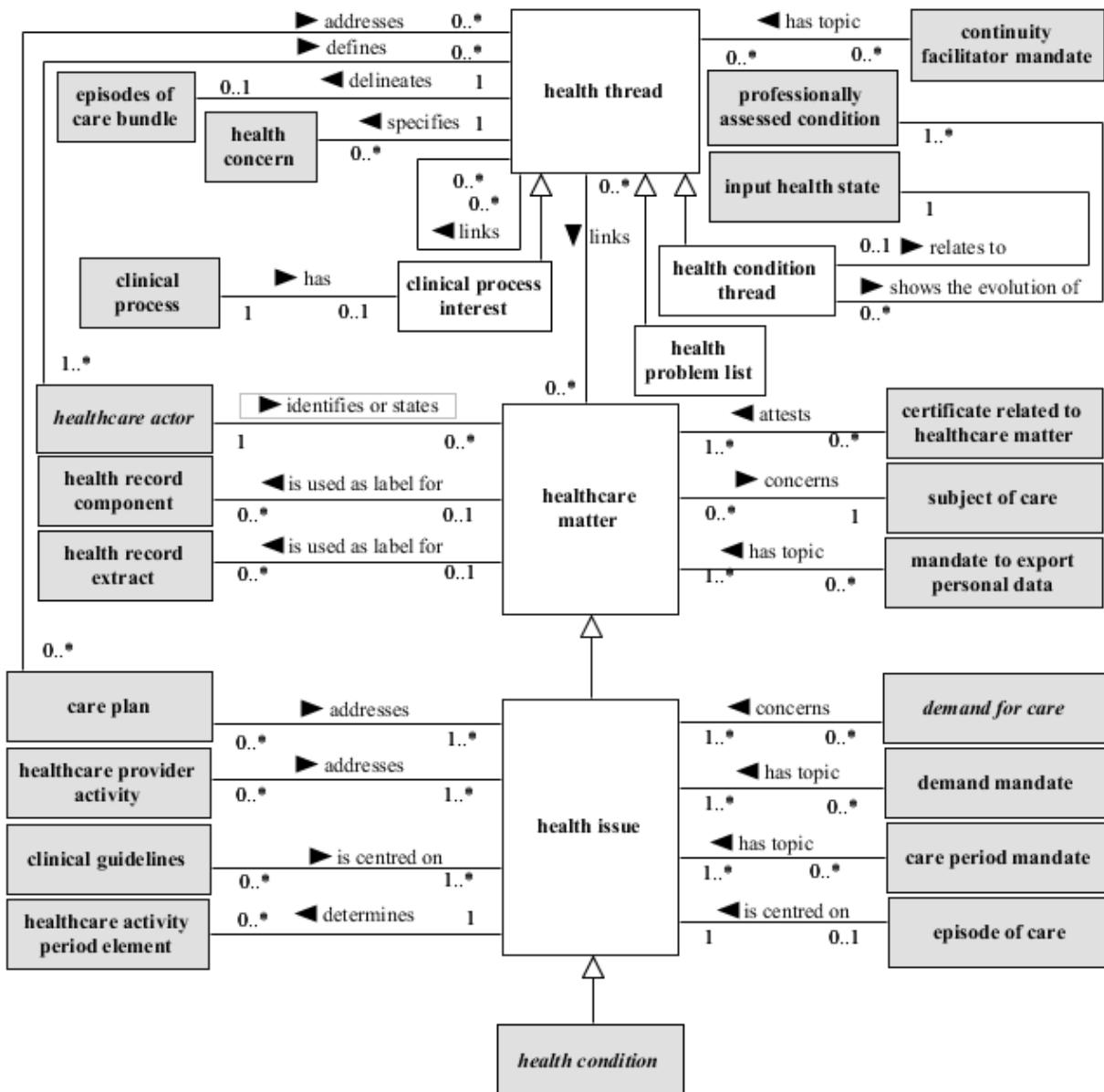


Figure 18 — Comprehensive UML diagram of health issues and health threads

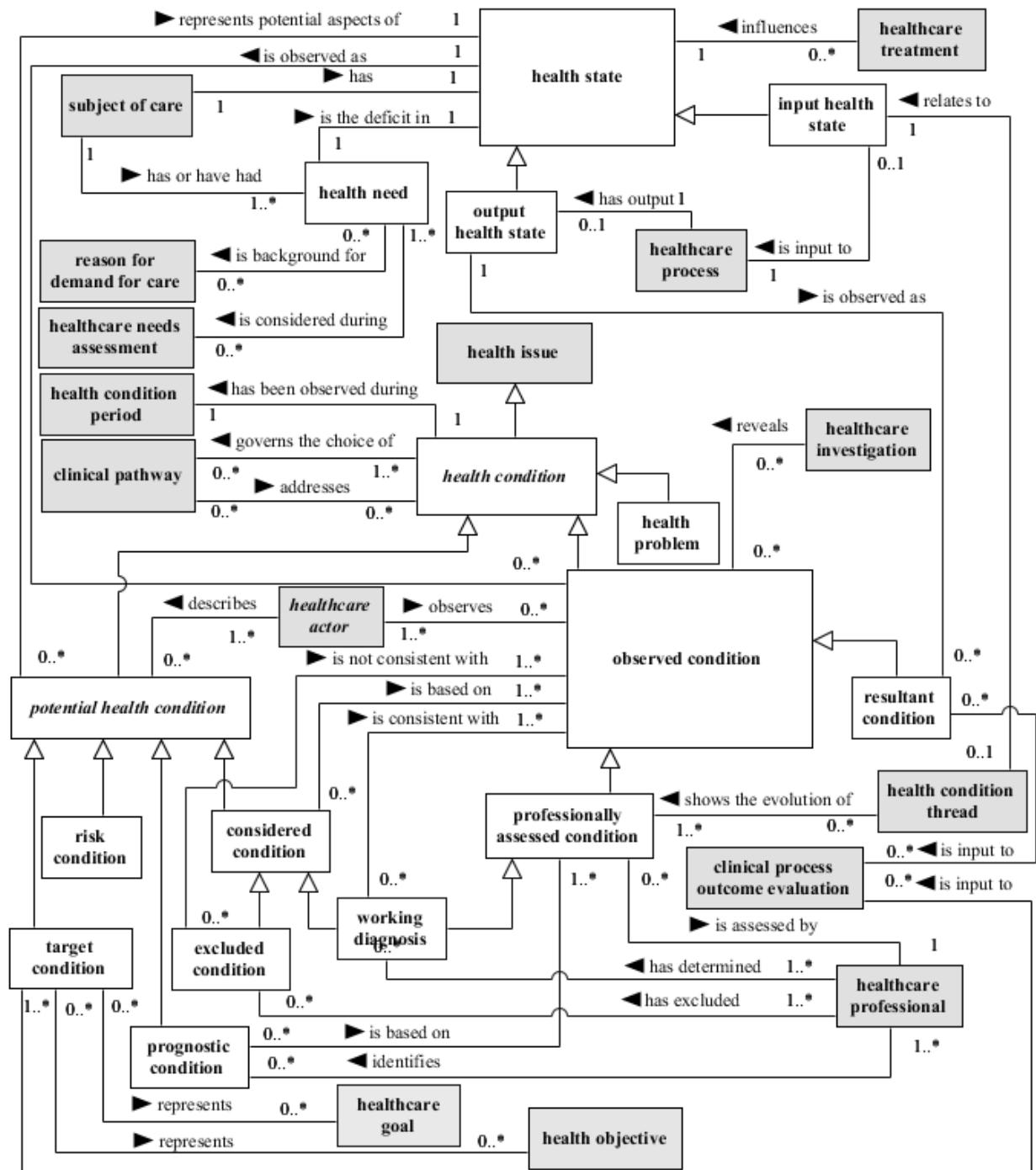


Figure 19 — Comprehensive UML diagram of health states and health conditions

6.2 Healthcare matter

Term:	<i>healthcare matter</i>
Definition: the representation of a matter related to the health of a <i>subject of care</i> and/or the provision of healthcare to that <i>subject of care</i> , as identified by one or more <i>healthcare actors</i>	
NOTE 1 <i>Healthcare matter</i> is a very broad and flexible concept that include anything related to the health or the healthcare of a <i>subject of care</i> . This means that <i>health conditions</i> , <i>healthcare activities</i> , <i>health problems</i> , the result of <i>healthcare activities</i> etc. all are possible <i>healthcare matters</i> . Thereby <i>healthcare matter</i> may have several specialisations.	
NOTE 2 According to this definition, a <i>healthcare matter</i> can represent a disease, an illness or another kind of <i>health condition</i> . In addition a <i>healthcare matter</i> may represent e.g. a request for a procedure (therapeutic or preventive) by the subject of care or another <i>healthcare actor</i> etc.	
NOTE 3 Concepts described and/or identified in a clinical terminology may represent types of <i>healthcare matter</i> .	
NOTE 4 Other specialisations of this concept than those included in this 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.	

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..* mandate to export personal data	has topic	1..*	healthcare matter
0..* health thread	links	0..*	healthcare matter
0..* certificate related to a healthcare matter	attests	1..*	healthcare matter

A model showing the associations of this concept is shown in Figure 20.

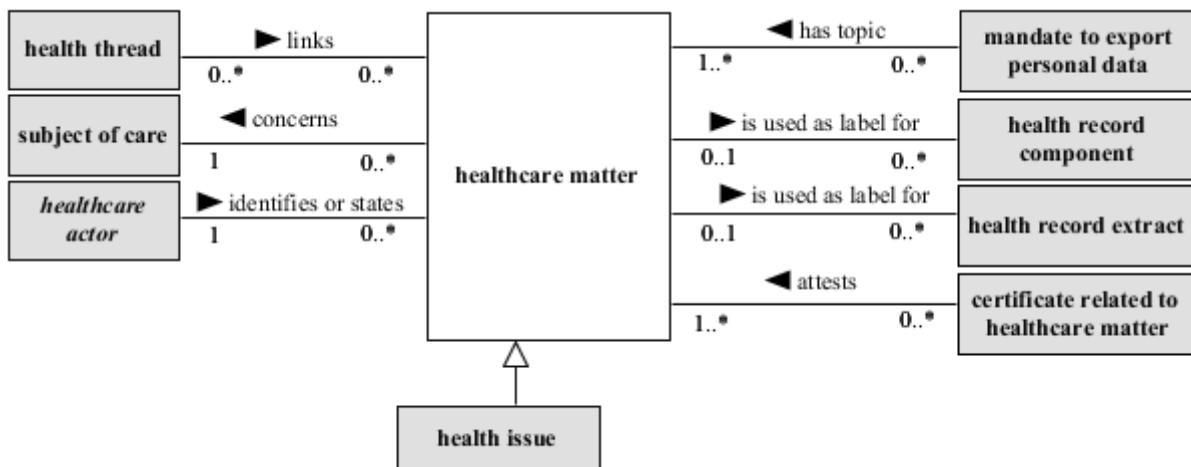


Figure 20 — Healthcare matter (UML representation)

6.3 Health issue

Term:	<i>health issue</i>					
Definition: <i>healthcare matter related to the health of a subject of care</i>						
NOTE 1 According to this definition, a <i>health issue</i> can correspond to a health problem, a disease, an illness or another kind of <i>health condition</i> .						
EXAMPLES A loss of weight, a heart attack, a drug addiction, an injury, dermatitis.						
Specialization of	Generalization of					
healthcare matter	health condition					
Association from	Association name	Association to				
1 health issue	determines	0..*	healthcare activity period element			
0..* care plan	addresses	1..*	health issue			
0..1 episode of care	is centred on	1	health issue			
0..* healthcare provider activity	addresses	1..*	health issue			
0..* demand mandate	has topic	1..*	health issue			
0..* care period mandate	has topic	1..*	health issue			
0..* demand for care	concerns	1..*	health issue			
0..* clinical guidelines	is centred on	1..*	health issue			

A model showing the associations of this concept is shown in Figure 21.

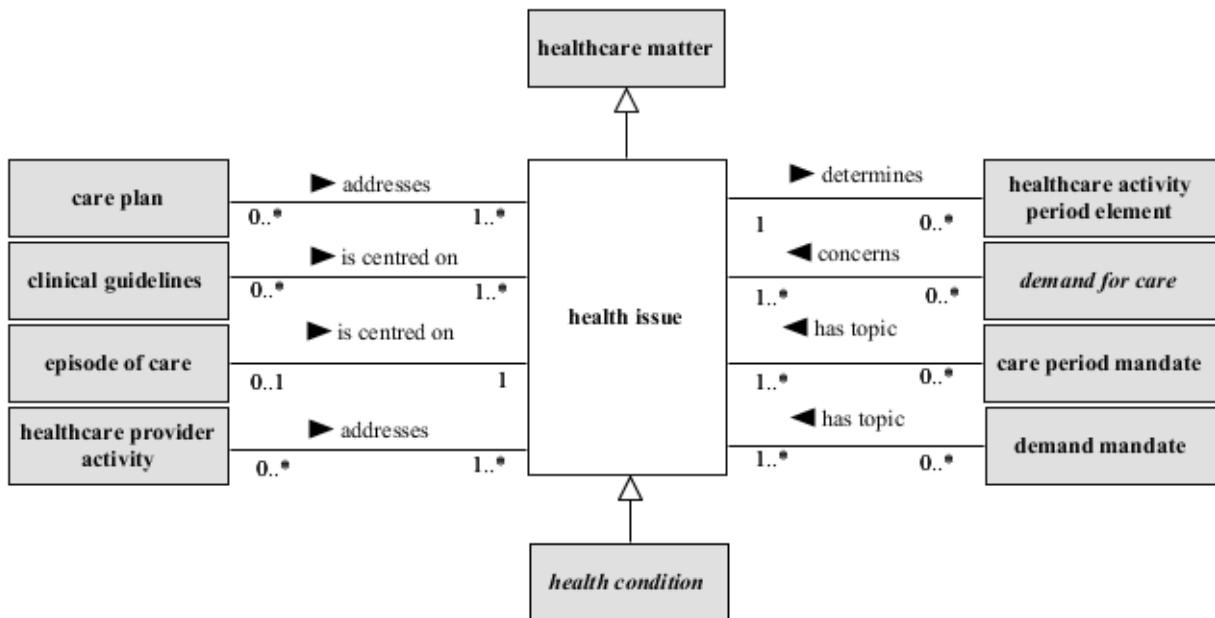


Figure 21 — Health issue (UML representation)

6.3.1 Health state

Term:	<i>health state</i>	
Definition: physical and mental functions, body structure, personal factors, activity, participation and environmental aspects as the composite health of a <i>subject of care</i>		
NOTE 1 A perception of a <i>health state</i> is a <i>health condition</i> . A <i>health state</i> may possibly give way to more than one perception, resulting in more than one <i>health condition</i> . The underlying <i>health state</i> is nevertheless present even if not perceived by an observer, e.g. the <i>subject of care</i> 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.		
Specialization of	Generalization of	
	input health state	
	output health state	
Association from	Association name	Association to
1 subject of care	has	1 health state
1 health state	is observed as	0..* observed condition
0..* potential health condition	represents potential aspects of	1 health state
0..* healthcare treatment	is influencing	1 health state
1 health need	is the deficit in	1 health state

A model showing the associations of this concept is shown in Figure 22.

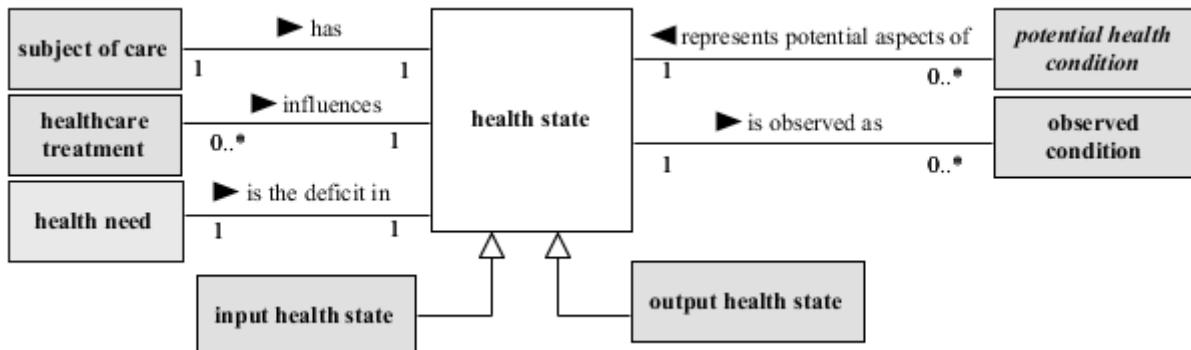


Figure 22 — Health state (UML representation)

6.3.1.1. Input health state

Term:	<i>input health state</i>	
Definition:	<i>health state at the initiation of healthcare process</i>	
NOTE The <i>output health state</i> from one <i>healthcare process</i> may be the <i>input health state</i> to a subsequent <i>healthcare process</i> .		
Specialization of	Generalization of	
health state		
Association from	Association name	Association to
0..1 health condition thread	relates to	1 input health state
0..1 input health state	is input to	1 healthcare process

A model showing the associations of this concept is shown in Figure 23.

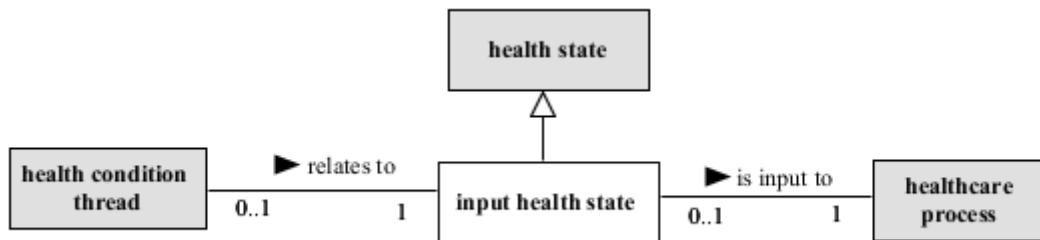


Figure 23 — Input health state (UML representation)

6.3.1.2. Output health state

Term:	<i>output health state</i>	
Synonym:	outcome	
Definition:	health state when a <i>healthcare process</i> ends	
NOTE The <i>output health state</i> from one <i>healthcare process</i> may be the <i>input health state</i> to a subsequent <i>healthcare process</i> .		
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

A model showing the associations of this concept is shown in Figure 24.

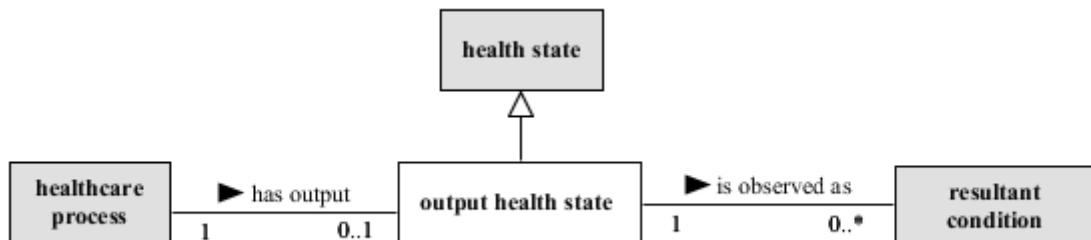


Figure 24 — Output health state (UML representation)

6.3.1.3. Health need

Term:	<i>health need</i>		
Synonyms:	need for an improved health state, health related need, health state need		
Definition:	gap between the current <i>health state</i> and a desired future <i>health state</i>		
NOTE 1 A <i>health need</i> is the deficit in a human being's <i>health state</i> . NOTE 2 The current <i>health state</i> is observed as <i>observed conditions</i> . NOTE 3 The desired future <i>health state</i> can be a <i>health objective</i> expressed as <i>target conditions</i> . NOTE 4 The <i>health need</i> can be identified and formulated by the <i>subject of care</i> or by any other <i>healthcare actor</i> . NOTE 5 <i>Health needs</i> are the motivations/indications for <i>healthcare activities</i> and are the basic input to <i>healthcare needs assessments</i> .			
Association from	Association name	Association to	
1 subject of care	has or have 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	
1 health need	is a deficit in	1 health state	

A model showing the associations of this concept is shown in Figure 25.

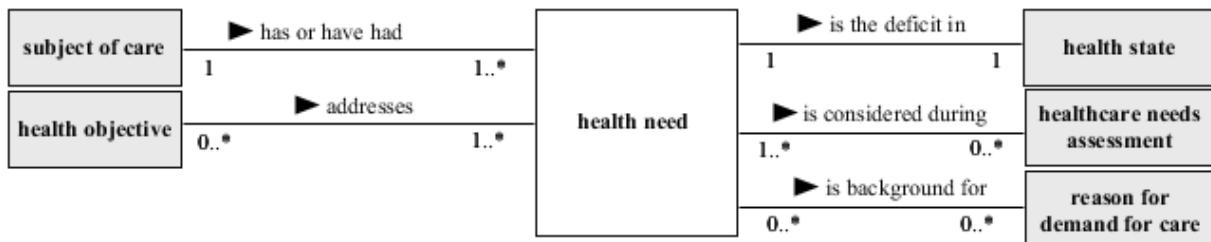


Figure 25 — Health need (UML representation)

6.3.2 Health condition

Term:	<i>health condition</i>															
Definition: one or more observed or potential aspects of the <i>health state</i> at a given time																
NOTE 1 In the perspective of healthcare, the term <i>health condition</i> is often used to label a harmful or adverse condition (diseases, disorders, injuries, etc.), because it may motivate certain <i>healthcare activities</i> .																
NOTE 2 A <i>health state</i> is an object, a perception of which is a <i>health condition</i> . The underlying <i>health state</i> is nevertheless present even if not perceived by an observer, e.g. the <i>subject of care</i> having a cancer before it gives symptoms.																
NOTE 3 In a <i>clinical process</i> , the <i>health state</i> of the <i>subject of care</i> is process input and also the process output. The evolving <i>health state</i> follows a life cycle and along its successive steps, is observed as different <i>health conditions</i> : initial, <i>observed condition</i> , <i>professionally assessed condition</i> , <i>resultant condition</i> (the outcome of the process), evaluated.																
NOTE 4 A diagnosis is a way to describe certain types of <i>health conditions</i> .																
NOTE 5 <i>Health condition</i> may relate to a past, present or potential future <i>health state</i> .																
EXAMPLES A health problem, diagnosis: an acute myocardial infarction (<i>professionally assessed condition</i>); a symptom: a head ache (<i>observed condition</i>).																
<table border="1"> <thead> <tr> <th>Specialization of</th> <th>Generalization of</th> </tr> </thead> <tbody> <tr> <td>health issue</td> <td>observed condition</td> </tr> <tr> <td></td> <td>potential health condition</td> </tr> <tr> <td></td> <td>health condition</td> </tr> </tbody> </table>		Specialization of	Generalization of	health issue	observed condition		potential health condition		health condition							
Specialization of	Generalization of															
health issue	observed condition															
	potential health condition															
	health condition															
<table border="1"> <thead> <tr> <th>Association from</th> <th>Association name</th> <th>Association to</th> </tr> </thead> <tbody> <tr> <td>1 health condition</td> <td>has been observed during</td> <td>1 health condition period</td> </tr> <tr> <td>1..* health condition</td> <td>governs the choice of</td> <td>0..* clinical pathway</td> </tr> <tr> <td>0..* health condition thread</td> <td>shows the evolution of</td> <td>1..* health condition</td> </tr> <tr> <td>0..* clinical pathway</td> <td>addresses</td> <td>1..* health condition</td> </tr> </tbody> </table>		Association from	Association name	Association to	1 health condition	has been observed during	1 health condition period	1..* health condition	governs the choice of	0..* clinical pathway	0..* health condition thread	shows the evolution of	1..* health condition	0..* clinical pathway	addresses	1..* health condition
Association from	Association name	Association to														
1 health condition	has been observed during	1 health condition period														
1..* health condition	governs the choice of	0..* clinical pathway														
0..* health condition thread	shows the evolution of	1..* health condition														
0..* clinical pathway	addresses	1..* health condition														

A model showing the associations of this concept is shown in Figure 26.

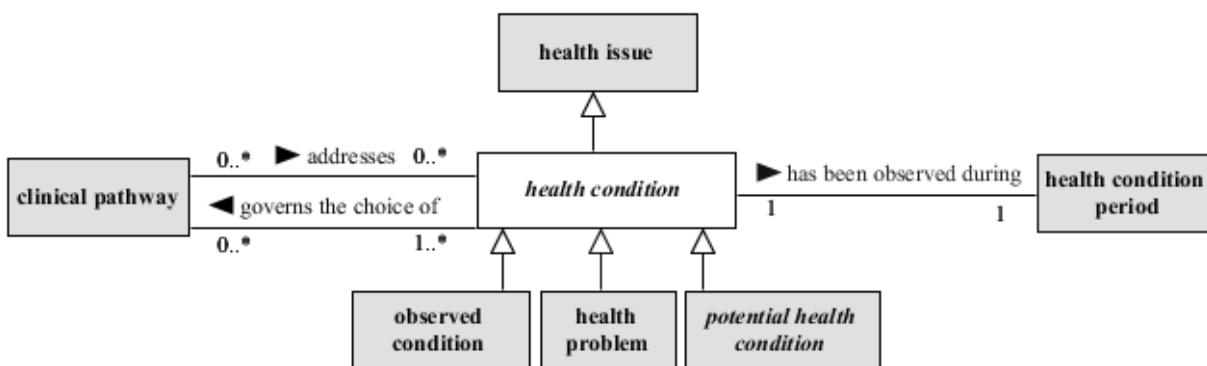


Figure 26 — Health condition (UML representation)

6.3.2.1. Observed condition

Term:	<i>observed condition</i>	
Synonym:	observed health condition	
Definition: <i>health condition observed by a healthcare actor</i>		
NOTE <i>Healthcare professionals and subjects of care are examples of healthcare actors that can perceive the observed aspect of a health state.</i>		
EXAMPLES: A blood pressure, a swelling in the abdomen, tachycardia, body weight, lung infiltration on x-ray, a haemoglobin value, pale skin.		
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
0..* considered condition	is based on	1..* observed condition
0..* healthcare investigation	reveals	0..* observed condition
1..* healthcare actor	observes	0..* observed condition
0..* working diagnosis	is consistent with	1..* observed condition
0..* excluded condition	is not consistent with	1..* observed condition

A model showing the associations of this concept is shown in Figure 27.

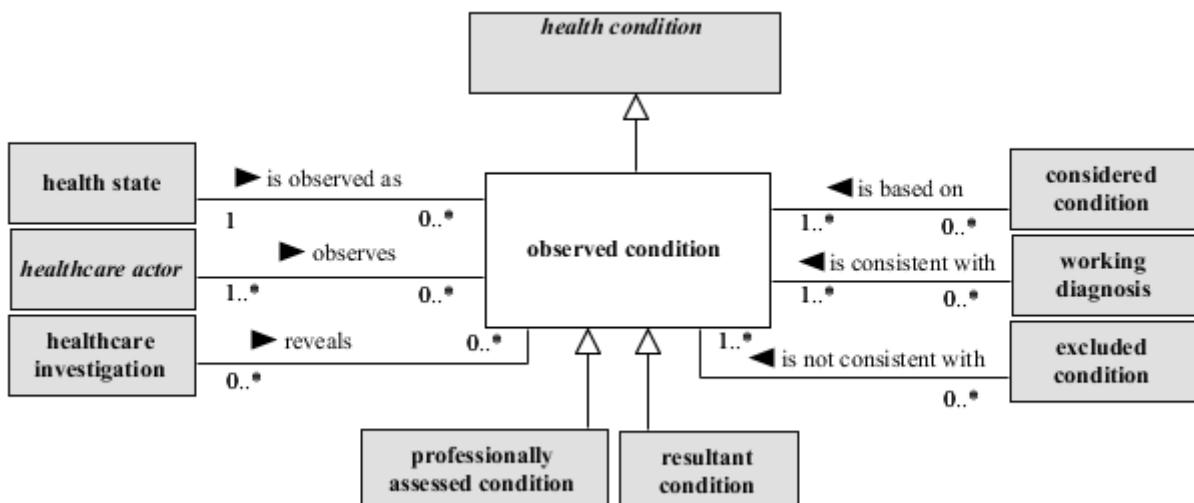


Figure 27 — Observed condition (UML representation)

6.3.1.2.1 Resultant condition

Term:	<i>resultant condition</i>	
Synonym:	healthcare process result, healthcare activity result	
Definition:	<i>observed condition representing the output health state</i>	
<p>NOTE 1 EXAMPLES</p>		
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

A model showing the associations of this concept is shown in Figure 28.

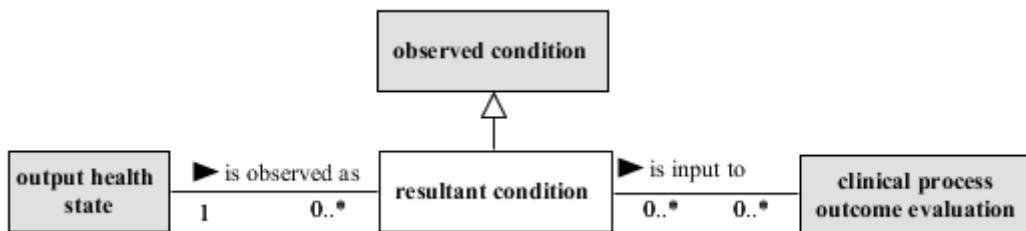


Figure 28 — Resultant condition (UML representation)

6.3.1.2.2 Professionally assessed condition

Term:	<i>professionally assessed condition</i>	
Synonym:	professionally assessed health condition	
Definition: <i>observed condition assessed by a healthcare professional concerning the genesis , the course, the severity or the impact of the health statee</i>		
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 assessed by	1 healthcare professional

A model showing the associations of this concept is shown in Figure 29.

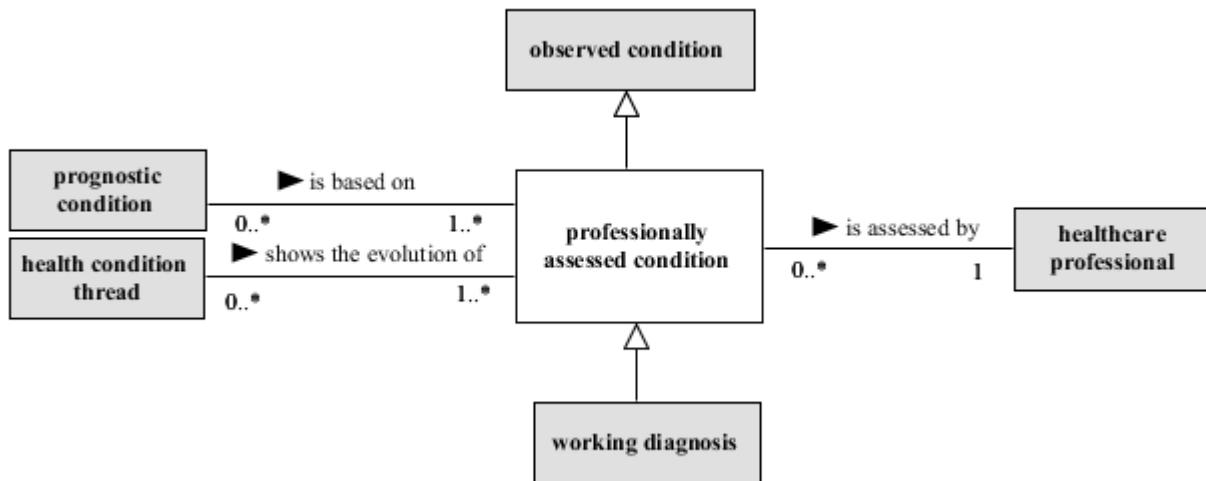


Figure 29 — Professionally assessed condition (UML representation)

6.3.2.2. Potential health condition

Term:	<i>potential health condition</i>	
Definition: possible future or current <i>health condition</i> described by a <i>healthcare actor</i>		
NOTE 1 A <i>potential health condition</i> is not yet observed, but represents an imagined, possible observation of aspects of a current or future health state.		
NOTE 2 A <i>potential health condition</i> can only be fully supported through the use of one of its specializations.		
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

A model showing the associations of this concept is shown in Figure 30.

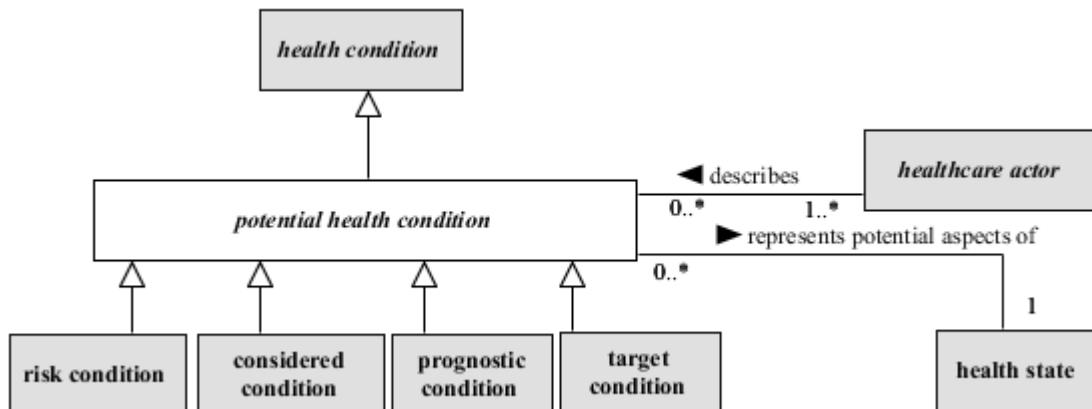


Figure 30 — Potential health condition (UML representation)

6.3.2.2.1 Considered condition

Term: <i>considered condition</i>		
Synonym: <i>considered health condition</i>		
Definition: <i>potential health condition</i> considered by a <i>healthcare actor</i> on the basis of one or more <i>observed conditions</i>		
NOTE 1 A request for care normally includes a <i>health condition</i> or symptom observed by the <i>subject of care</i> and also a question about what the reason for that symptom might be. This <i>potential health condition</i> in this question (the <i>health condition</i> behind the symptom) that is called a <i>considered condition</i> .		
NOTE 2 A <i>referral</i> within a <i>clinical process</i> is normally motivated by one or several <i>observed conditions</i> and/or <i>professionally assessed conditions</i> . However the <i>referral</i> also normally includes a question that the <i>healthcare investigation</i> is supposed to get an answer to. The question formulated as a <i>potential condition</i> is a <i>considered condition</i> .		
NOTE 3 A <i>considered condition</i> remain considered until the associated <i>observed conditions</i> are changed or completed. <i>Healthcare investigation</i> and/or <i>healthcare treatment</i> result in new observations that can verify or not verify the (suspected) <i>considered condition</i> . When a <i>considered condition</i> is verified it is transformed into a <i>working diagnosis</i> . If a <i>considered condition</i> cannot be verified by relevant <i>healthcare activities</i> it is transformed into an <i>excluded condition</i> .		
NOTE 4 A <i>working diagnosis</i> is often identified in the clinical process as a summary after the planned <i>healthcare investigation</i> are completed. A <i>working diagnosis</i> in this stage is often called a <i>diagnosis</i> . An <i>excluded condition</i> could correspondingly be called a negation of a <i>diagnosis</i> .		
EXAMPLES Diagnostic hypothesis, any candidate in a differential diagnosis set		
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

A model showing the associations of this concept is shown in Figure 31.

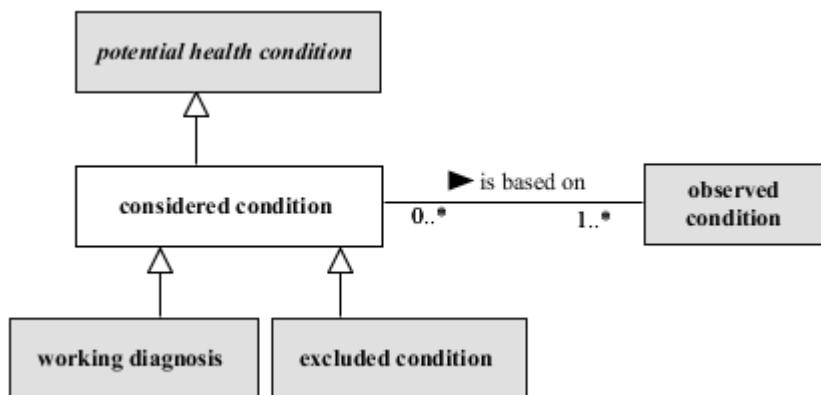


Figure 31 — Considered condition (UML representation)

6.3.2.2.2 Excluded condition

Term:	<i>excluded condition</i>	
Synonym:	discounted condition, non-verified condition, rule out condition	
Definition: <i>considered condition</i> that one or more <i>healthcare professionals</i> have determined not to be consistent with the known <i>observed conditions</i>		
NOTE 1		
EXAMPLES		
Specialization of	Generalization of	
considered condition		
Association from	Association name	Association to
1..* healthcare professional	has excluded	0..* excluded condition
0..* excluded condition	is not consistent with	1..* observed condition

A model showing the associations of this concept is shown in Figure 32.

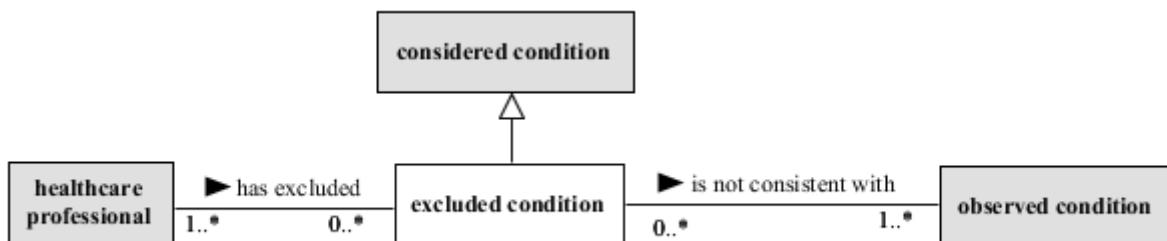


Figure 32 — Excluded condition (UML representation)

6.3.2.2.3 Working diagnosis

Term:	<i>working diagnosis</i>	
Synonym:	working hypothesis	
Definition: <i>professionally assessed condition that one or more healthcare professionals have determined to be the most consistent with the known observed conditions</i>		
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

A model showing the associations of this concept is shown in Figure 33.

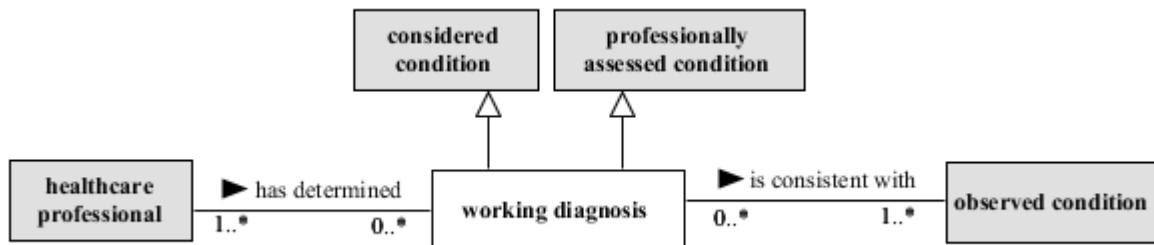


Figure 33 — Working diagnosis (UML representation)

6.3.2.2.4 Target condition

Term:	<i>target condition</i>	
Synonym:	target health condition, intended outcome	
Definition: <i>potential health condition representing health objectives and/or healthcare goals</i>		
NOTE Assessment of needs for <i>healthcare activities</i> includes identification of <i>health objectives</i> and/or <i>healthcare goals</i> . These inform decisions about relevant activities to create or update the <i>care plan</i> .		
EXAMPLE 1	The <i>target condition</i> 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 <i>target condition</i> of a newly diagnosed diabetic adolescent boy is maintenance of their HbA1c at 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).	
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

A model showing the associations of this concept is shown in Figure 34.

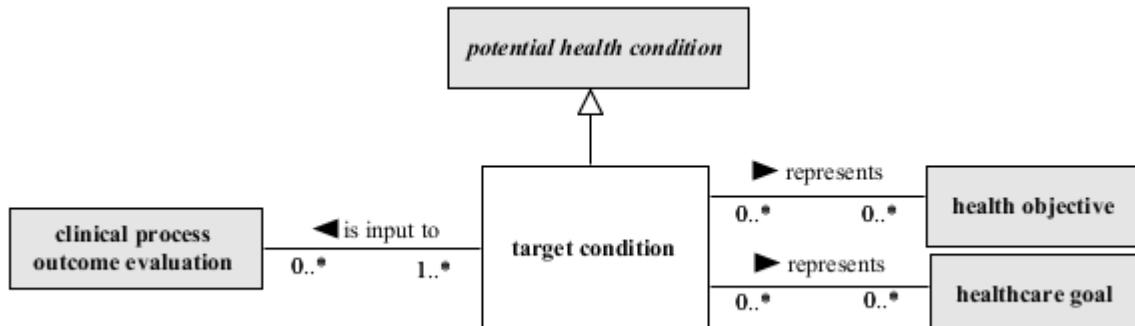


Figure 34 — Target condition (UML representation)

6.3.2.2.5 Prognostic condition

Term:	<i>prognostic condition</i>	
Synonym:	prognostic health condition	
Definition: <i>potential health condition</i> representing the anticipated course of a <i>health state</i> assessed by <i>healthcare professionals</i>		
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

A model showing the associations of this concept is shown in Figure 35.

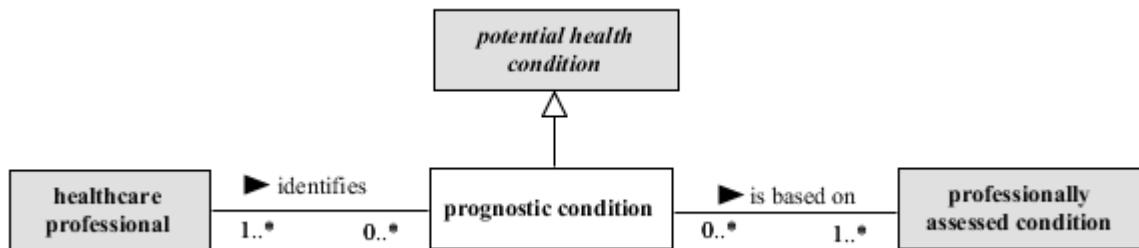


Figure 35 — Prognostic condition (UML representation)

6.3.2.2.6 Risk condition

Term:	<i>risk condition</i>
Synonym:	<i>risk health condition</i>
Definition: <i>potential health condition</i> representing an undesirable future <i>health state</i>	
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.	
Specialization of	Generalization of
potential health condition	

A model showing the associations of this concept is shown in Figure 36.

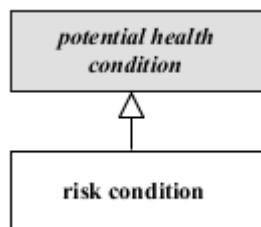


Figure 36 — Risk condition (UML representation)

6.3.2.3. Health problem

Term:	<i>health problem</i>
Synonym:	
Definition:	<i>health condition</i> considered by a <i>health care actor</i> to be a problem
NOTE	<i>Health problems</i> can be single observations but are usually more compound as a summary of several observations. Single observations are often criteria for the more compound <i>health condition</i> considered to be a <i>health problem</i> .
EXAMPLES	Diabetes, stroke, heredity for breast cancer.
Specialization of	Generalization of
health condition	

A model showing the associations of this concept is shown in Figure 37.

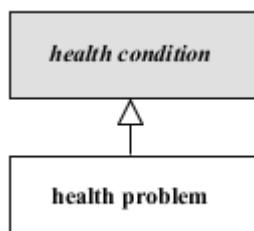


Figure 37 — Health problem (UML representation)

6.4 Health thread

Term:	<i>health thread</i>
Definition: association between <i>healthcare matters</i> defined by one or several <i>healthcare actors</i>	
NOTE 1 A <i>health thread</i> reconciles a range of <i>healthcare matters</i> reflecting the variety of scopes of <i>healthcare actors</i> , particularly of <i>healthcare providers</i> .	
NOTE 2 A <i>health thread</i> inherently associates the <i>healthcare processes</i> as well as the <i>healthcare activity period elements</i> referring to those <i>healthcare matters</i> .	
NOTE 3 A <i>health thread</i> may be established by a team (e.g. a coordination committee).	
NOTE 4 A <i>health thread</i> can be built step-by-step, by allowing each <i>healthcare professional</i> to add their perspective into a common <i>health thread</i> .	
NOTE 7 Under the responsibility of a designated <i>healthcare actor</i> , a <i>health thread</i> linking several <i>health issues</i> can describe an <i>episodes of care bundle</i> , i.e. a partial or comprehensive synthesis of <i>healthcare actor related episodes of care</i> .	
NOTE 8 A collective decision (before, during or after the healthcare interventions) may define a <i>health thread</i> and so the idea of the 'episode' accepted by all the <i>healthcare professionals</i> involved.	
NOTE 9 Two <i>health issues</i> may sometimes only be recognized as belonging to the same <i>health thread</i> late in the process of care. Conversely, two <i>health issues</i> thought initially to belong to the same <i>health thread</i> may need to be separated later.	
NOTE 10 Since a <i>health thread</i> links any number of <i>health issues</i> ; it also may link <i>health threads</i> linking other <i>health issues</i> . Hence, a <i>health thread</i> may be considered an aggregation of <i>health issues</i> and/or <i>health threads</i> .	
EXAMPLES	
<ul style="list-style-type: none"> • 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 <i>health conditions</i> included in a <i>healthcare process</i>. 	
Specialization of	Generalization of
	clinical process interest
	health condition thread
	health problem list

Association from	Association name	Association to	
1 health thread	delineates	0..1	episodes of care bundle
1 health thread	specifies	0..*	health concern
0..* health thread	links	0..*	health issue
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

A model showing the associations of this concept is shown in Figure 38.

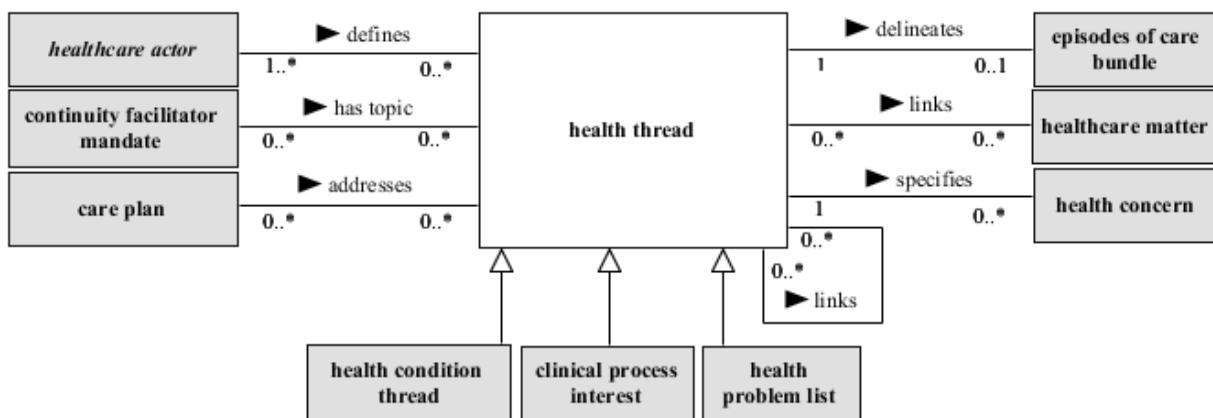


Figure 38 — Health thread (UML representation)

6.4.1 Clinical process interest

Term:	<i>clinical process interest</i>	
Definition: <i>health thread</i> that includes all the <i>healthcare matters</i> related to a specific <i>clinical process</i>		
NOTE 1 A <i>clinical process interest</i> makes it possible		
	<ul style="list-style-type: none"> • to make all information related to the <i>healthcare issues matters</i> in a <i>clinical process</i> available to all <i>healthcare actors</i> that have the needs for that and to support continuity of care • for documentation concerning a <i>clinical process</i> to follow the <i>subject of care</i> across borders of <i>healthcare providers</i> and organizational units and as such avoid unnecessary duplication of documentation • to track all information in a <i>clinical processes</i> for secondary use of data in follow up • to follow the value adding by <i>healthcare activities</i> by documented changes in <i>health conditions</i> during all stages of the <i>clinical process</i> • to constrain the availability of information related to a certain <i>clinical process</i> due to the integrity needs for the <i>subject of care</i> 	
Specialization of	Generalization of	
health thread		
Association from	Association name	Association to
1 clinical process	has	0..1 clinical process interest

A model showing the associations of this concept is shown in Figure 39.

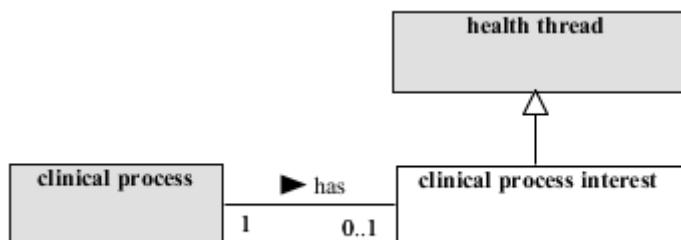


Figure 39 — Clinical process interest (UML representation)

6.4.1.1. Health problem list

Term: <i>health problem list</i>	
Synonym: healthcare problem list	
Definition: <i>health thread that links a set of health problems</i>	
Specialization of	Generalization of
health thread	

A model showing the associations of this concept is shown in Figure 40.

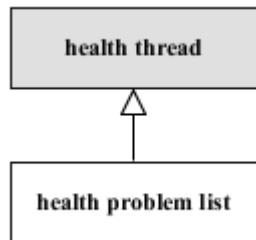


Figure 40 — Health problem list (UML representation)

6.4.1.2. Health condition thread

Term:	<i>health condition thread</i>	
Definition: <i>health thread</i> that shows the evolution of <i>health conditions</i> during a <i>healthcare process</i> , starting with the <i>health condition</i> that represents the <i>input health state</i>		
Specialization of		Generalization of
health thread		
Association from	Association name	Association to
0..1 health condition thread	relates to	1 input health state
0..* health condition thread	shows the evolution of	1..* health condition

A model showing the associations of this concept is shown in Figure 41.

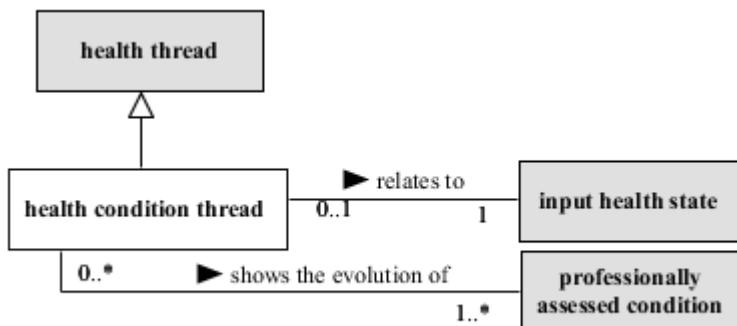


Figure 41 — Health condition thread (UML representation)

7. Time-related concepts in continuity of care

7.1 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 42.

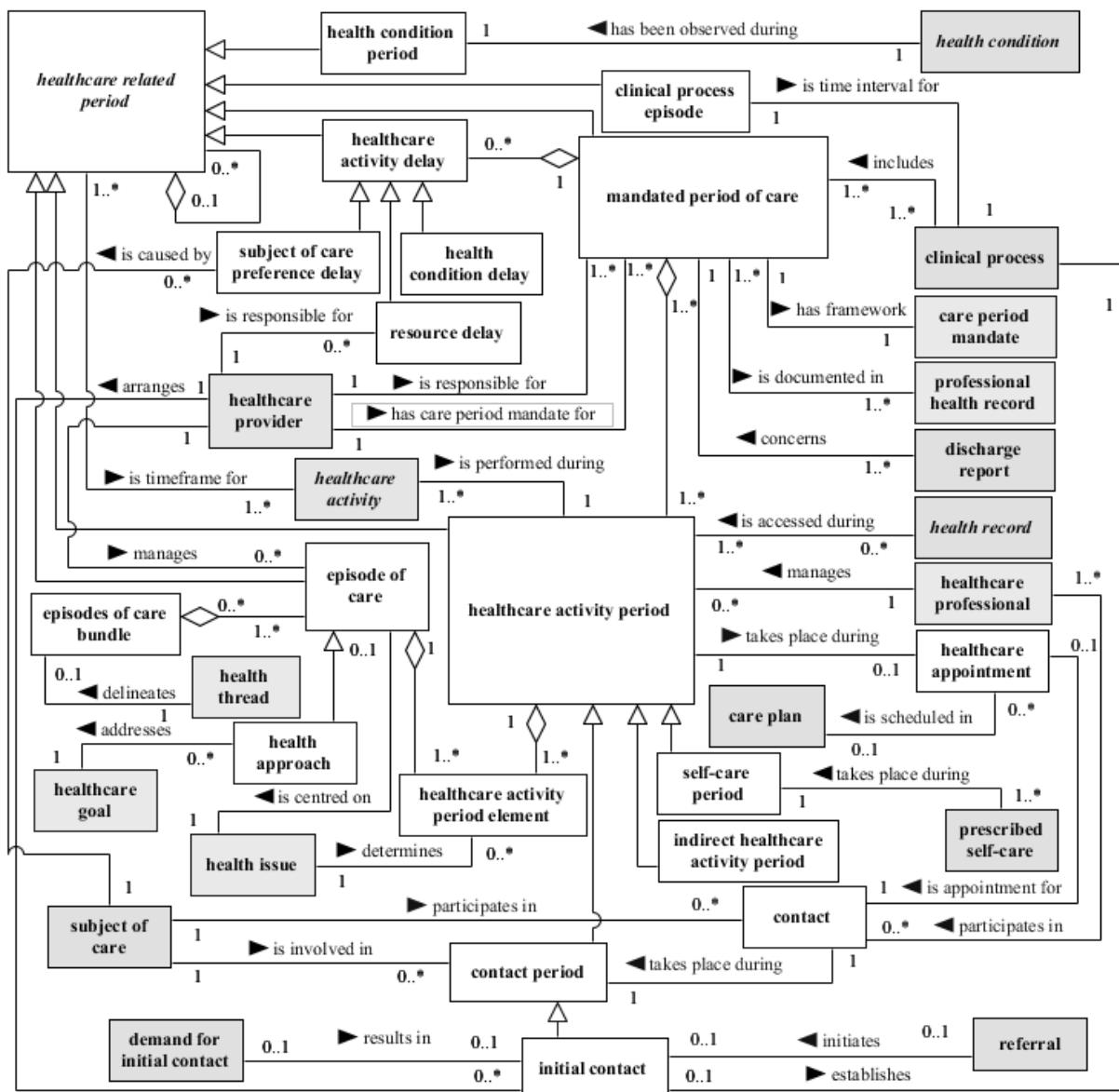


Figure 42 — Comprehensive UML diagram of time-related concepts in continuity of care

7.2 Mandated period of care

Term:	<i>mandated period of care</i>					
Synonym:	commissioned period of care					
Deprecated terms:	period of care, period of healthcare					
Definition: set of <i>healthcare activity periods</i> in the framework of a <i>care period mandate</i>						
NOTE 1 The <i>mandated period of care</i> is focused upon the framework of a care commitment of the provider as well as the mandate from the <i>subject of care</i> , which means that the roles and responsibilities of both the interacting parts are respected.						
NOTE 2 Whenever the <i>healthcare provider</i> considered in a <i>mandated period of care</i> is a <i>healthcare organization</i> , this <i>mandated period of care</i> encompasses all <i>healthcare activity periods</i> with <i>healthcare professionals</i> who have a role in that <i>healthcare organization</i> .						
NOTE 3 A <i>mandated period of care</i> may be part of another <i>mandated period of care</i> .						
NOTE 4 In EN 13940-1:2007 period of care was the preferred term for this concept.						
NOTE 5 Relevant information describing and produced during the <i>healthcare activities</i> performed as a part of a <i>mandated period of care</i> are recorded in one or more <i>professional health records</i> .						
EXAMPLES	A hospital stay, a series of radiotherapy sessions at an outpatient clinic.					
Specialization of health related period	Generalization of					
Component of	Aggregation of					
	1..*	healthcare activity period				
	0..*	healthcare activity delay				
Association from	Association name	Association to				
1	mandated period of care	has framework	1	care period mandate		
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		

A model showing the associations of this concept is shown in Figure 43.

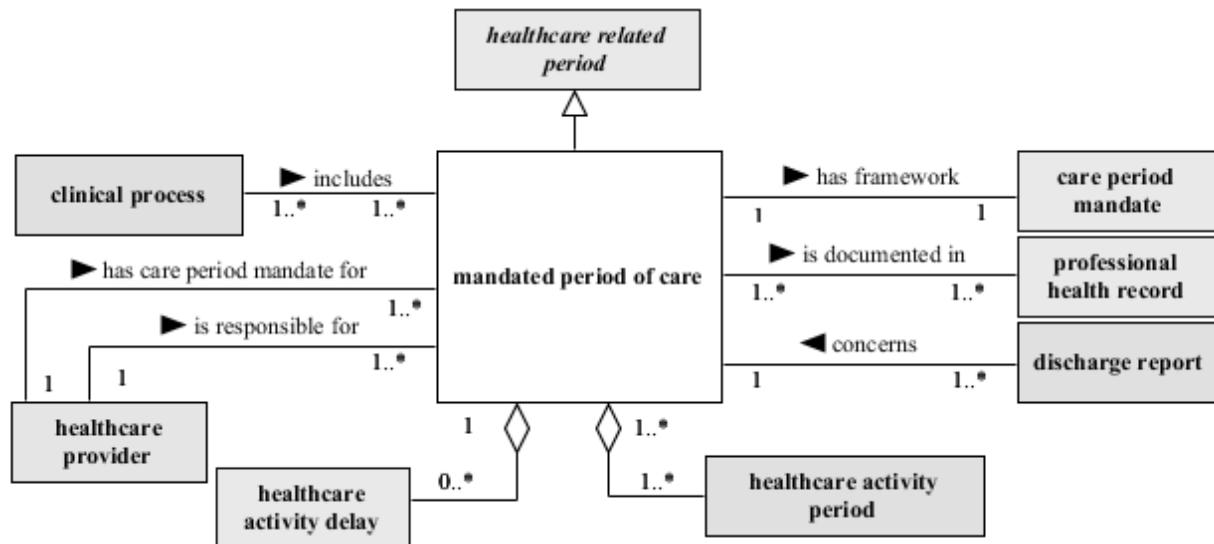


Figure 43 — Mandated period of care (UML representation)

7.2.1 Healthcare activity period

Term:	<i>healthcare activity period</i>		
Deprecated term:	contact		
Definition:	time interval during which <i>healthcare activities</i> are performed for a <i>subject of care</i>		
NOTE	In EN 13940-1:2007 contact was the preferred term for this concept.		
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	
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

A model showing the associations of this concept is shown in Figure 44.

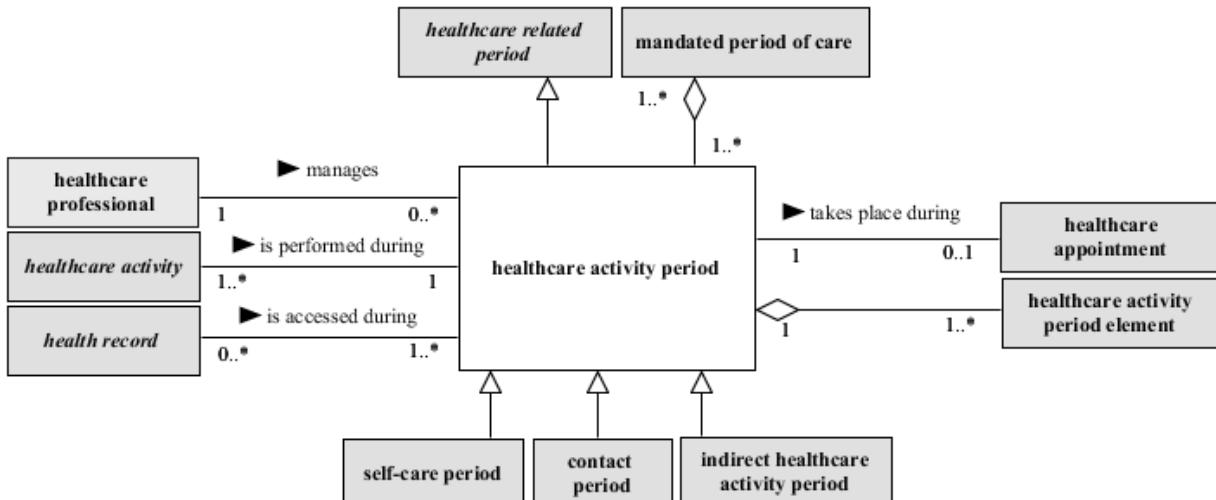


Figure 44 — Healthcare activity period (UML representation)

7.2.1.1. Contact

Term:	<i>contact</i>		
Synonym:			
Definition:	interaction between a <i>subject of care</i> and one or more <i>healthcare professionals</i>		
NOTE			
EXAMPLES			
Association from	Association name	Association to	
1 contact	takes place during	1	contact period
1 subject of care	participates in	0..*	contact
1..* healthcare professional	participates in	0..*	contact
0..1 healthcare appointment	is appointment for	1	contact

A model showing the associations of this concept is shown in Figure 45.

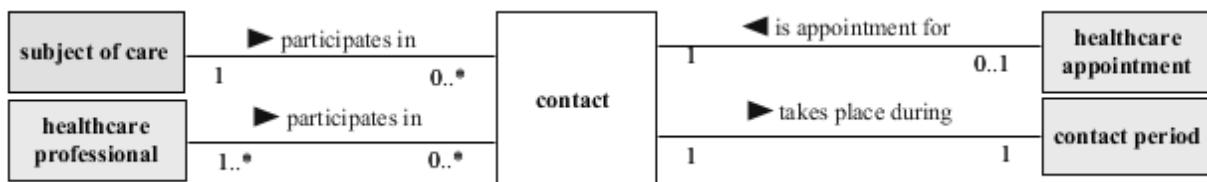


Figure 45 — Contact (UML representation)

7.2.1.2. Contact period

Term: contact period		
Synonym: healthcare contact, 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.		
Specialization of	Generalization of	
healthcare activity period	initial contact	
Association from	Association name	Association to
1 subject of care	is involved in	0..* contact period
1 contact	takes place during	1 contact period

A model showing the associations of this concept is shown in Figure 46.

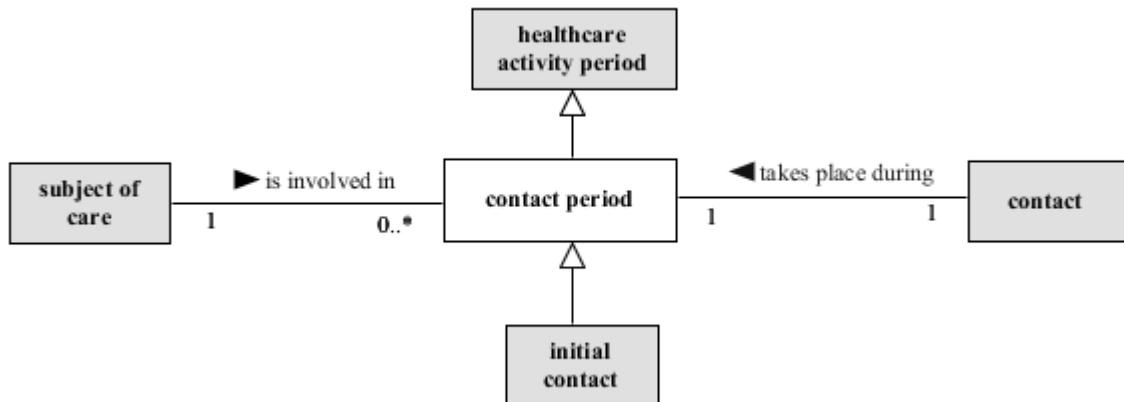


Figure 46 — Contact period (UML representation)

7.2.1.3. Indirect healthcare activity period

Term:	<i>indirect healthcare activity period</i>
Deprecated term:	record contact
Definition: <i>healthcare activity period</i> without the involvement of the <i>subject of care</i>	
NOTE 1 In EN 13940-1:2007 the concept record contact was defined as ' <i>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</i> '.	
EXAMPLE 1 The period where 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	
Specialization of	Generalization of
healthcare activity period	

A model showing the associations of this concept is shown in Figure47.

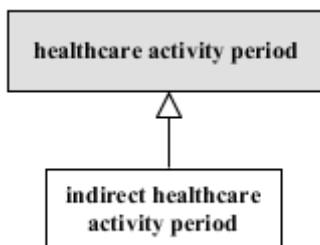


Figure 47 — Indirect healthcare activity period (UML representation)

7.2.1.4. Self-care period

Term:	<i>self-care period</i>	
Definition:	<i>healthcare activity period where prescribed self-care is performed</i>	
Specialization of		
healthcare activity period		
Association from	Association name	Association to
1..* prescribed self-care	takes place during	1 self-care period

A model showing the associations of this concept is shown in Figure 48.

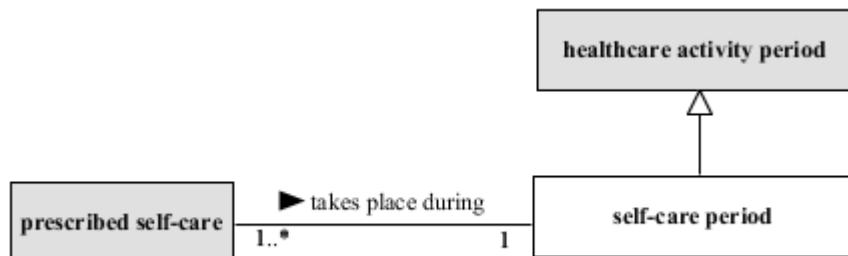


Figure 48 — Self-care period (UML representation)

7.2.1.5. Initial contact

Term:	<i>initial contact</i>		
Definition:	<i>contact</i> during which a <i>clinical process</i> is established		
Specialization of	Generalization of		
contact period			
Association from	Association name	Association to	
0..1 initial contact	establishes	1	clinical process
0..1 referral	initiates	0..1	initial contact
0..1 demand for initial contact	results in	0..1	initial contact
1 healthcare provider	arranges	0..*	initial contact

A model showing the associations of this concept is shown in Figure 49.

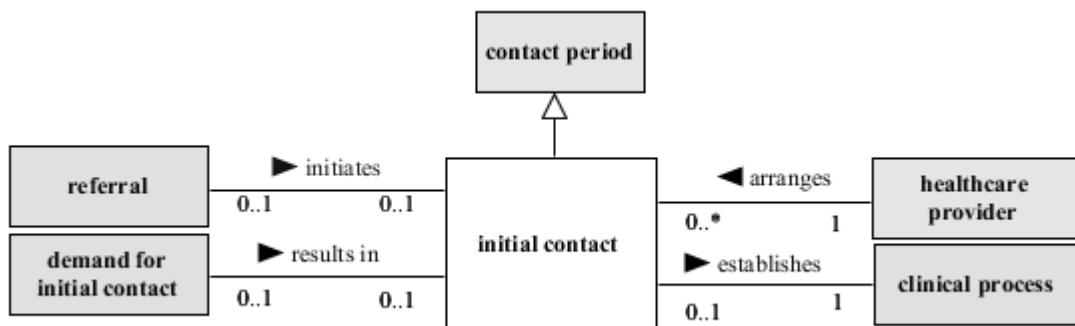


Figure 49 — Initial contact (UML representation)

7.2.2 Healthcare activity period element

Term: <i>healthcare activity period element</i>		
Deprecated term: contact element		
Definition: part of a <i>healthcare activity period</i> during which one <i>health issue</i> is specifically addressed		
NOTE 1 Several <i>healthcare activity period elements</i> may take place during the course of a <i>healthcare activity period</i> .		
NOTE 2 A <i>healthcare activity period element</i> is part of only one <i>healthcare activity period</i> and of only one <i>episode of care</i> .		
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, besides another part of the same consultation devoted to the treatment of diabetes mellitus.		
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

A model showing the associations of this concept is shown in Figure 50.

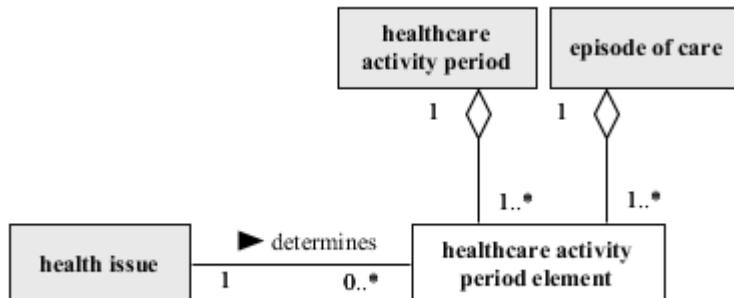


Figure 50 — Healthcare activity period element (UML representation)

7.2.3 Healthcare appointment

Term:	<i>healthcare appointment</i>		
Definition:	appointment for a <i>contact</i>		
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

A model showing the associations of this concept is shown in Figure 51.



Figure 51 — Healthcare appointment (UML representation)

7.3 Health related period

Term:	<i>health related period</i>	
Definition: time interval related to the health of a <i>subject of care</i> .		
NOTE 1 A <i>health related period</i> may be specialized in relation to a number of situations – a specific <i>clinical process</i> , <i>healthcare professional</i> , a specific department, a specific <i>health issue</i> etc.		
NOTE 2 A <i>health related period</i> is delineated by a 'start date and time' and a '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.		
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	
Association from	Association name	Association to
1..* health related period	is timeframe for	1..* healthcare activity

A model showing the associations of this concept is shown in Figure 52.

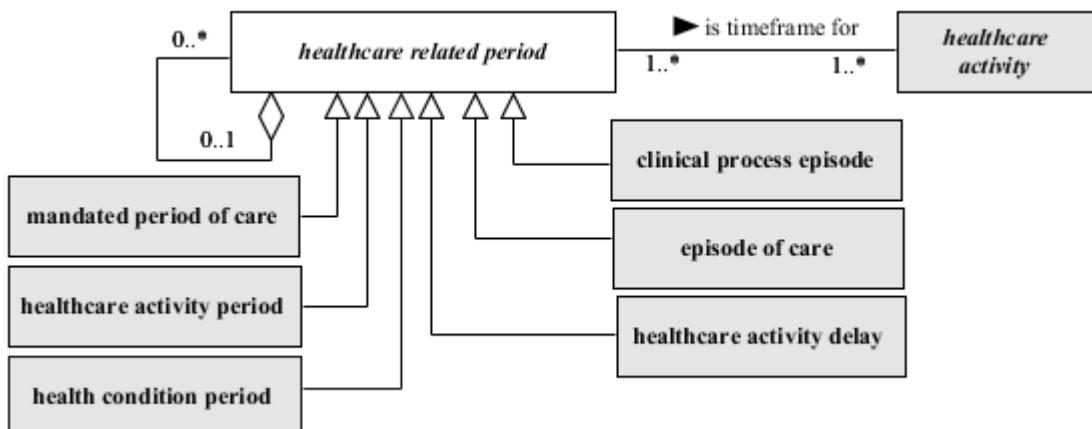


Figure 52 — Health related period (UML representation)

7.3.1 Health condition period

Term:	<i>health condition period</i>			
Synonym:				
Definition: time interval during which a <i>health condition</i> has been observed				
NOTE 1 Observation of a <i>health condition</i> may lead to an <i>episode of care</i>				
NOTE 2 Health condition period refers only to the observation of the health condition e.g. the time interval during which a subject of care has observed a bleeding. The concept episode of care is referring to the healthcare activities.				
Specialization of	Generalization of			
health related period				
Association from	Association name	Association to		
1 health condition	has been observed during	1 health condition period		

A model showing the associations of this concept is shown in Figure 53.

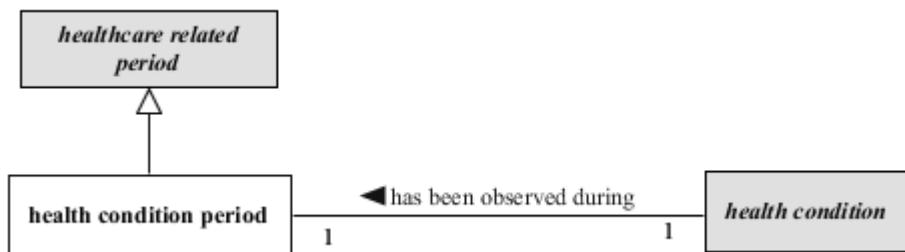


Figure 53 — Health condition period (UML representation)

7.3.2 Healthcare activity delay

Term:	<i>healthcare activity delay</i>
Definition: health related period during which a <i>healthcare activity</i> is planned but not started	
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	

A model showing the associations of this concept is shown in Figure 54.

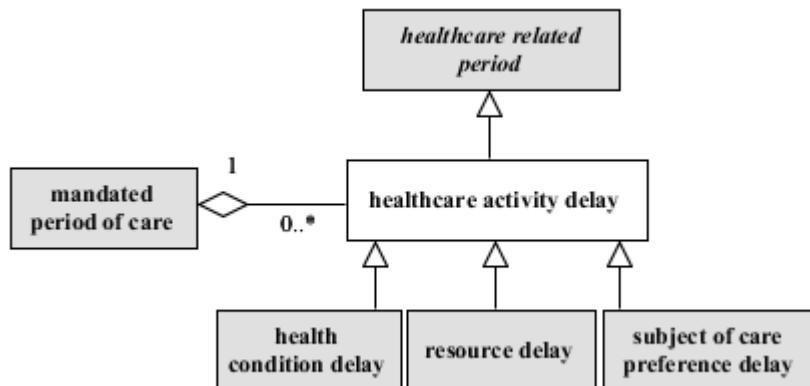


Figure 54 — Healthcare activity delay (UML representation)

7.3.2.1. Health condition delay

Term:	<i>health condition delay</i>
Definition: <i>healthcare activity delay caused by a health condition</i>	
EXAMPLE 1: surgery delayed because the subject of care is pregnant	
EXAMPLE 2: cervical examination delayed during menstruation	
Specialization of	Generalization of
healthcare activity delay	

A model showing the associations of this concept is shown in Figure 55.

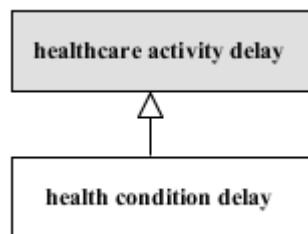


Figure 55 — Health condition delay (UML representation)

7.3.2.2. Resource delay

Term:	<i>resource delay</i>	
Definition: <i>healthcare activity delay</i> caused by resource constraints where there is no <i>health condition delay</i>		
EXAMPLE 1: activity scheduled later than clinically indicated to allow resources to be deployed on other subjects of care (a waiting list)		
EXAMPLE 2: activity postponed while necessary financial resources are identified		
Specialization of	Generalization of	
healthcare activity delay		
Association from	Association name	Association to
1 healthcare provider	is responsible for	0..* resource delay

A model showing the associations of this concept is shown in Figure 56.

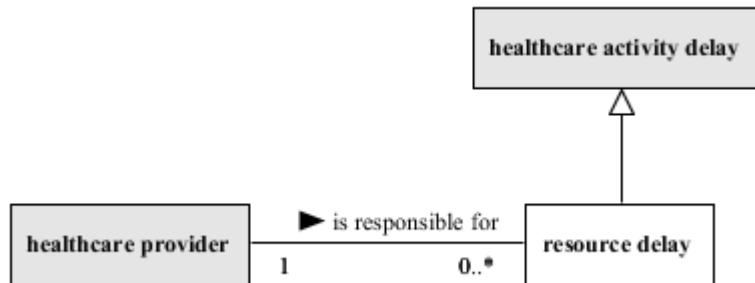


Figure 56 — Resource delay (UML representation)

7.3.2.3. Subject of care preference delay

Term:	<i>subject of care preference delay</i>	
Definition: <i>healthcare activity delay</i> by the preference of the <i>subject of care</i> , where there are neither <i>health condition delays</i> nor <i>resource delays</i>		
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		
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

A model showing the associations of this concept is shown in Figure 57.

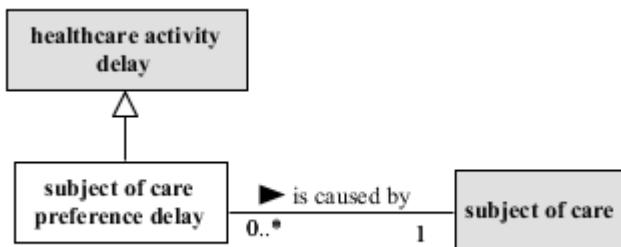


Figure 57 — Subject of care preference delay (UML representation)

7.3.3 Episode of care

Term:	<i>episode of care</i>	
Synonyms:	episode of healthcare, health issue related episode	
Definition: <i>health related period during which healthcare activities are performed to address one health issue as identified by one healthcare professional</i>		
NOTE 1 An <i>episode of care</i> encompasses all <i>healthcare activity period elements</i> related to the same <i>health issue</i> .		
NOTE 2 An <i>episode of care</i> starts with the very first <i>contact</i> with a <i>healthcare provider</i> for a <i>health issue</i> and it ends after the completion of all <i>healthcare activities</i> related to the last <i>contact</i> with that <i>healthcare provider</i> for the same <i>health issue</i> .		
NOTE 3 For practical reasons (e.g. the need to state start and end dates) and also because it relates specifically to a <i>health issue</i> defined by a given <i>healthcare professional</i> , an <i>episode of care</i> does not necessarily coincide with an 'episode of illness' (or of disease, or of any other kind of <i>health issue</i>).		
NOTE 4 During a <i>mandated period of care</i> several <i>health issues</i> may be handled and as such be linked to several <i>episodes of care</i> . These <i>episodes of care</i> are said to be 'concurrent'.		
EXAMPLES	An episode of urinary tract infection, an episode of cholecystectomy.	
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

A model showing the associations of this concept is shown in Figure 58.

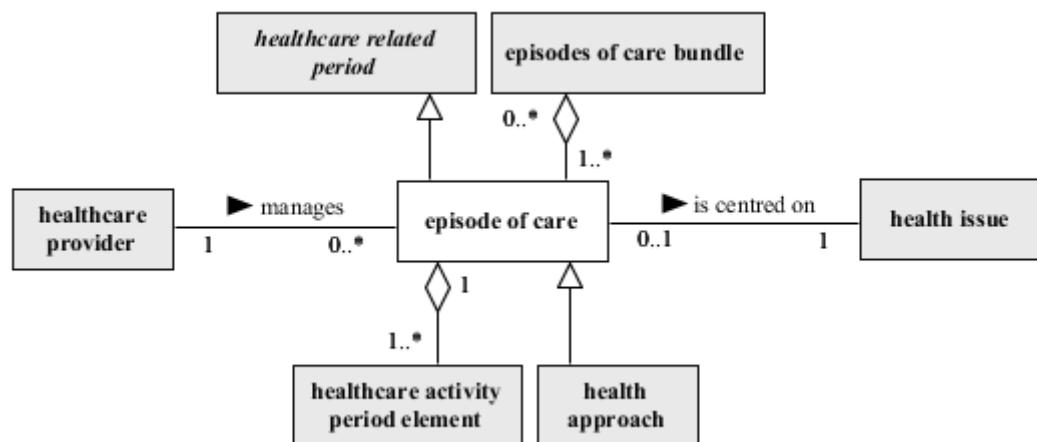


Figure 58 — Episode of care (UML representation)

7.3.3.1. Health approach

Term:	<i>health approach</i>	
Synonym:	healthcare approach, goal-addressing episode of care	
Definition: <i>episode of care</i> during which the <i>healthcare activities</i> performed address one specific <i>healthcare goal</i>		
Specialization of	Generalization of	
episode of care		
Association from	Association name	Association to
0..* health approach	addresses	1 healthcare goal

A model showing the associations of this concept is shown in Figure 59.

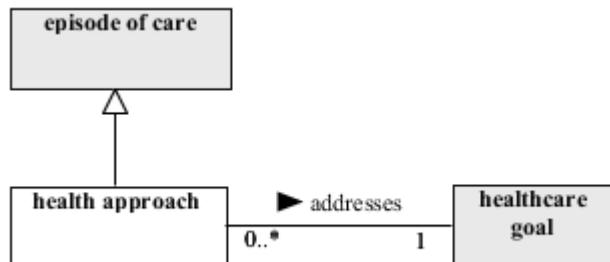


Figure 59 — Health approach (UML representation)

7.3.4 Clinical process episode

Term:	<i>clinical process episode</i>	
Definition: episode that includes all <i>healthcare activities</i> performed in one <i>clinical process</i>		
Specialization of		Generalization of
health related period		
Association from	Association name	Association to
1 clinical process episode	is time interval for	1 clinical process

A model showing the associations of this concept is shown in Figure 60.

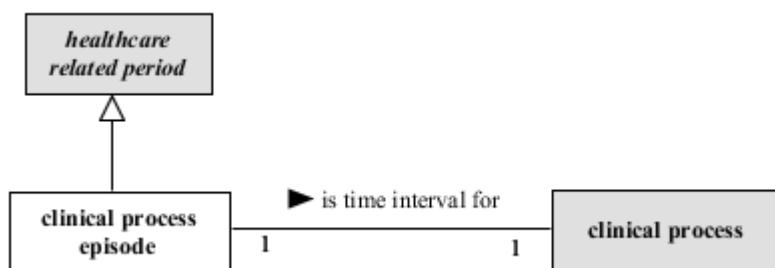


Figure 60 — Clinical process episode (UML representation)

7.4 Episodes of care bundle

Term:	<i>episodes of care bundle</i>										
Synonym:	episodes of healthcare bundle, cumulative episode of care										
Definition:	group of <i>episodes of care</i> delineated by a <i>health thread</i>										
<p>NOTE 1 An <i>episodes of care bundle</i> starts with the very first <i>contact</i> with a <i>healthcare provider</i> for a <i>health issue</i> considered in a <i>health thread</i> and ends after the completion of all <i>healthcare activities</i> related to the last <i>contact</i> with any <i>healthcare provider</i> for a <i>health issue</i> encompassed in the same <i>health thread</i>.</p> <p>NOTE 2 As different <i>health threads</i> may be considered that reconcile the perspectives of different <i>healthcare actors</i> (e.g. a care team manager, or a health authority) or sets of <i>healthcare actors</i>, there may exist different <i>health threads</i> according to the specific perspectives of those sets of <i>healthcare actors</i> that justify building up such <i>health threads</i>. As a consequence there may exist as many <i>episodes of care bundles</i> as there are such <i>health threads</i>.</p> <p>NOTE 3 From the electronic health record point of view, an <i>episodes of care bundle</i> shows the overall <i>healthcare activity period elements</i> related to those <i>health issues</i> that are linked by the same <i>health thread</i>.</p> <p>NOTE 4 In EN 13940-1:2007 cumulative episode of care was the preferred term for this concept.</p>											
EXAMPLES A cumulative episode of diabetes mellitus, a cumulative episode of breast cancer.											
<table border="1"> <thead> <tr> <th>Component of</th> <th>Aggregation of</th> </tr> </thead> <tbody> <tr> <td></td> <td>1..* episode of care</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Association from</th> <th>Association name</th> <th>Association to</th> </tr> </thead> <tbody> <tr> <td>1 health thread</td> <td>delineates</td> <td>0..1 episodes of care bundle</td> </tr> </tbody> </table>		Component of	Aggregation of		1..* episode of care	Association from	Association name	Association to	1 health thread	delineates	0..1 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									

A model showing the associations of this concept is shown in Figure 61.

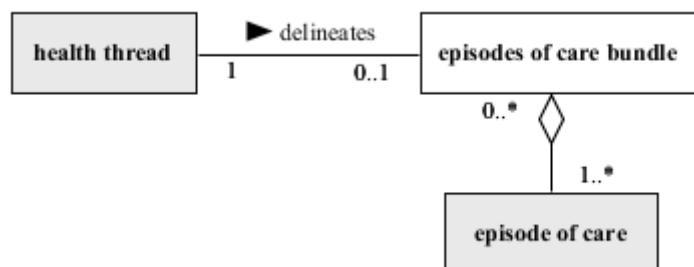


Figure 61 — Episodes of care bundle (UML representation)

8. Process related concepts

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 62.

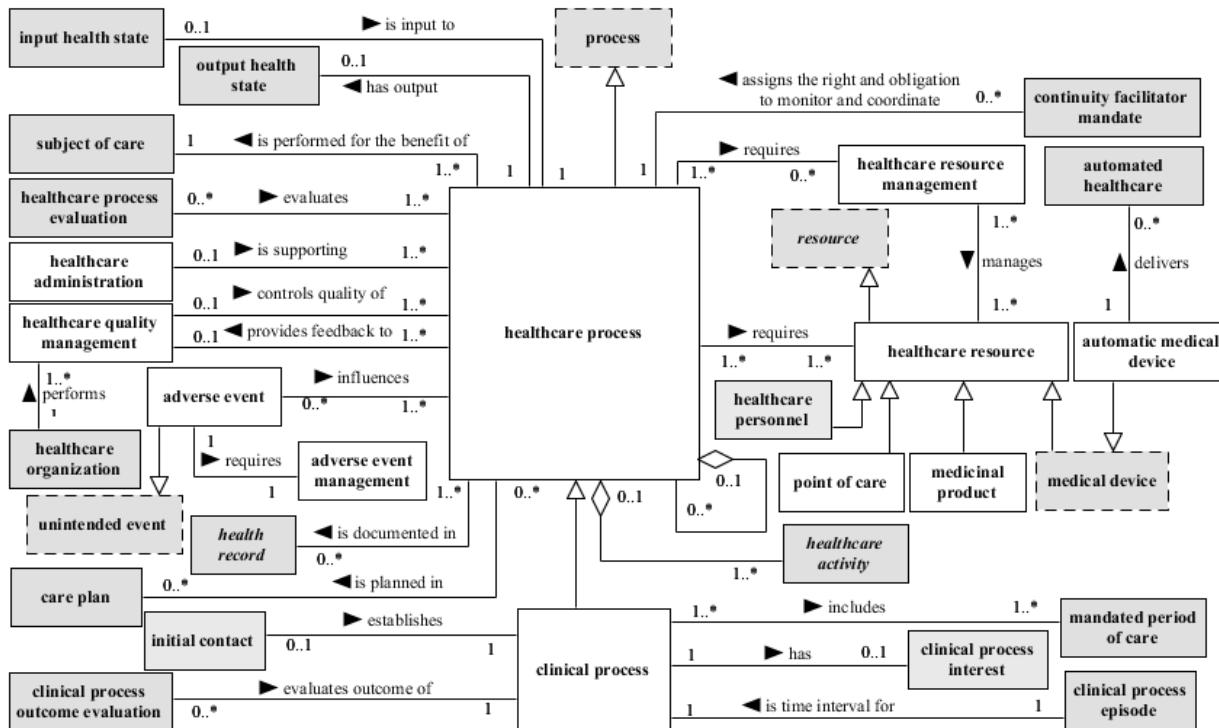


Figure 62 — Comprehensive UML diagram of process related concepts

8.2 Healthcare process

Term:	<i>healthcare process</i>					
Synonym:	care process					
Definition:	<i>process where healthcare activities are performed using healthcare resources</i>					
NOTE 1 The main kind of <i>healthcare process</i> is the <i>clinical process</i> that has a health state as input and output and includes all activities in relation to one or more specified <i>health issues</i> .						
NOTE 2 A <i>healthcare process</i> is not by definition restricted to one <i>healthcare provider</i> or any other organizational unit borders.						
Specialization of	Generalization of					
Process	clinical process					
Component of	Aggregation of					
0..* healthcare process	1..*	healthcare activity				
	0..*	healthcare process				
Association from	Association name		Association to			
1..* healthcare process	is performed for the benefit of		1 subject of care			
1..* healthcare process	is planned in		0..* care plan			
1..* healthcare process	requires		1..* healthcare resource			
0..* healthcare process evaluation	evaluates		1..* healthcare process			
0..* healthcare process	requires		0..* healthcare resource management			
1..* healthcare process	is documented in		0..* health record			
0..* healthcare process	has output		0..1 output health state			
1..* healthcare process	provides feedback to		0..1 healthcare quality management			
0..1 input health state	is input to		0..* healthcare process			
0..1 healthcare administration	is supporting		1..* healthcare process			
0..* continuity facilitator mandate	assigns the right and obligation to monitor and coordinate		1 healthcare process			
0..1 healthcare quality management	controls quality of		1..* healthcare process			
0..* adverse event	influences		1..* healthcare process			

A model showing the associations of this concept is shown in Figure 63.

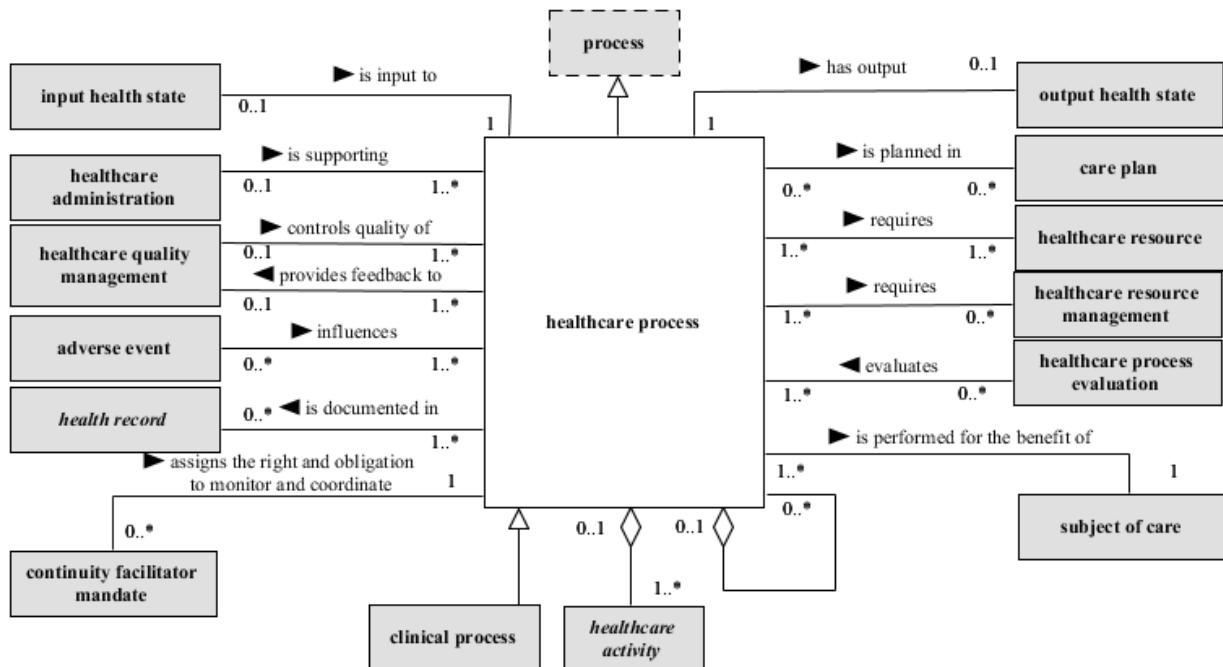


Figure 63 — Healthcare process (UML representation)

8.2.1 Clinical process

Term: *clinical process*

Definition: *healthcare process encompassing all healthcare provider activities and other prescribed healthcare activities that addresses health problems*

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 a health state of a *subject of care*.

NOTE 3 In a *clinical process* a *subject of care* and *healthcare professionals* interact in all types of *healthcare activities* concerning one or more *health issues*

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 kind 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 process). Secondary inputs can either be entirely consumed and disappear in the process or result either in refuse ('scoriae') or in objects re-usable in other processes of a different nature.

Specialization of		Generalization of	
healthcare process			
Association from		Association name	
1..*	clinical process	addresses	1..* health problem
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

A model showing the associations of this concept is shown in Figure 64.

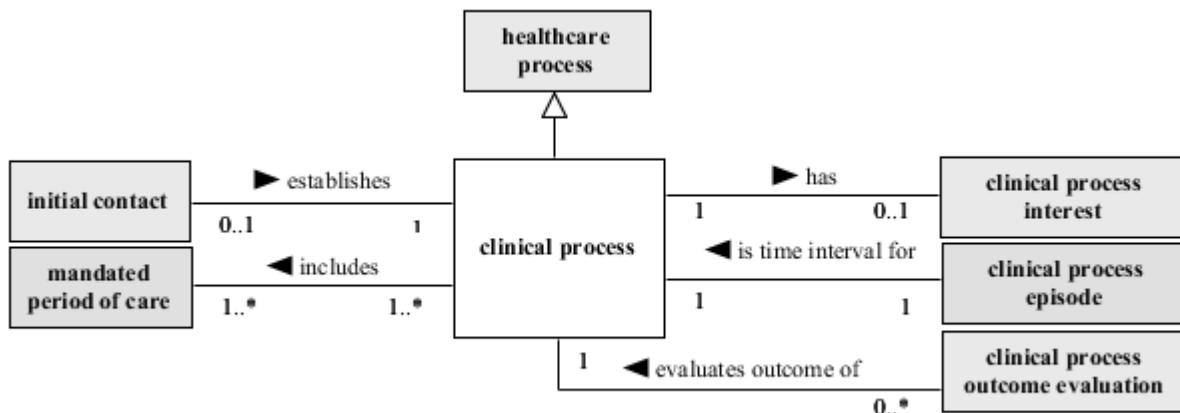


Figure 64 — Clinical process (UML representation)

8.3 Healthcare quality management

Term:	<i>healthcare quality management</i>		
Synonyms:	clinical governance,		
Definition:	coordinated activities to direct and control a <i>healthcare organization</i> with regard to quality		
<p>NOTE 1 The <i>clinical processes</i> are the most important type of <i>healthcare processes</i> related to <i>healthcare quality management</i>.</p> <p>NOTE 2 <i>Healthcare quality management</i> activities include the establishment of a quality policy, setting quality objectives and planning, the performance of audits, evaluation and a feedback loop for quality improvement, all resulting in quality assurance.</p> <p>NOTE 4 Quality management activities may be performed by other kinds of organizations than <i>healthcare organizations</i>.</p> <p>NOTE 5 This definition of quality management is an adaptation of the ISO 9000:2005 definition.</p>			
<p>EXAMPLES Fulfilling requirements in quality criteria repositories, changing behaviour of <i>healthcare professionals</i>.</p>			
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	

A model showing the associations of this concept is shown in Figure 65.

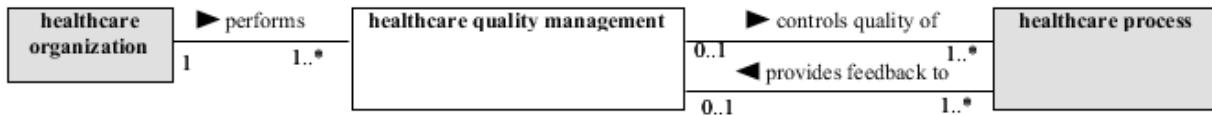


Figure 65 — Healthcare quality management (UML representation)

8.4 Healthcare resource management

Term: <i>healthcare resource management</i>			
Definition: activities to direct and control the supply of the resources required to perform <i>healthcare activities</i>			
Association from	Association name	Association to	
1..* healthcare resource management	manages	1..*	healthcare resource
1..* healthcare process	requires	0..*	healthcare resource management
1 healthcare provider	performs	0..*	healthcare resource management

A model showing the associations of this concept is shown in Figure 66.



Figure 66 — Healthcare resource management (UML representation)

8.5 Healthcare administration

Term:	<i>healthcare administration</i>	
Definition:	administrative activities related to <i>healthcare processes</i>	
NOTE Administrative activities are indirect activities in a <i>healthcare process</i> and include support and management.		
EXAMPLES	Budgeting and resource allocation, organizational structure, non-clinical documentation, administrative activity management, resource management etc.	
Association from	Association name	Association to
0..1 healthcare administration	is supporting	1..* healthcare process

A model showing the associations of this concept is shown in Figure 67.

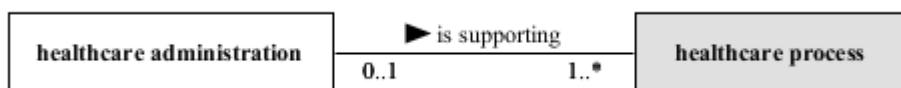


Figure 67 — Healthcare administration (UML representation)

8.6 Healthcare resource

Term: <i>healthcare resource</i>		
Definition: resource needed to perform <i>healthcare activities</i>		
NOTE 2 As a <i>healthcare process</i> develops, the <i>healthcare resources</i> follow a life cycle. Examples of steps of such a life cycle are: 'available', 'booked', 'provided', "in use", 'consumed', etc.		
EXAMPLES	<i>Healthcare professional</i> on duty, operation theatre, instruments ready to use, consultation rooms, bed in a ward, prepared medicinal products, Electrocardiography-device, blood sample, donated kidney etc.	
Specialization of	Generalization of	
resource	healthcare personnel	
	point of care	
	medicinal product	
	medical device	
Association from	Association name	Association to
1..* healthcare process	requires	1..* healthcare resource
1..* healthcare resource management	manages	1..* healthcare resource

A model showing the associations of this concept is shown in Figure 68.

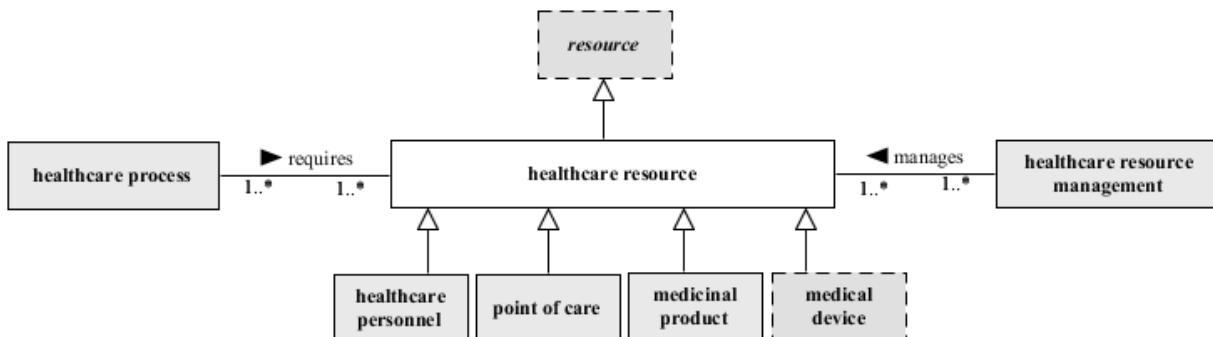


Figure 68 — Healthcare resource (UML representation)

8.6.1 Point of care

Term:	<i>point of care</i>
Definition:	location where direct <i>healthcare activities</i> are performed
NOTE	Location refers to the geographical location of the subject of care; not the body area that the treatment is applied to.
EXAMPLE	Surgery room, ward, ambulance, road side, home of the subject of care, school etc.

A model showing the associations of this concept is shown in Figure 69.

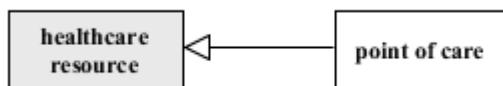


Figure 69 — Point of care (UML representation)

8.6.2 Automatic medical device

Term:	<i>automatic medical device</i>	
Definition: <i>medical device capable of performing automated healthcare activities</i>		
NOTE In EN 13940-1:2007 the concept <i>healthcare device</i> was a specialization of <i>healthcare actor</i> and defined as 'device or equipment, possibly including a piece of software, involved in the provision of <i>health care activities</i> '.		
EXAMPLE	A specific identifiable Electrocardiography machine, electronic blood-sugar monitor	
Specialization of	Generalization of	
medical device		
Association from	Association name	Association to
1 automatic medical device	performs	0..* automated healthcare

A model showing the associations of this concept is shown in Figure 70.

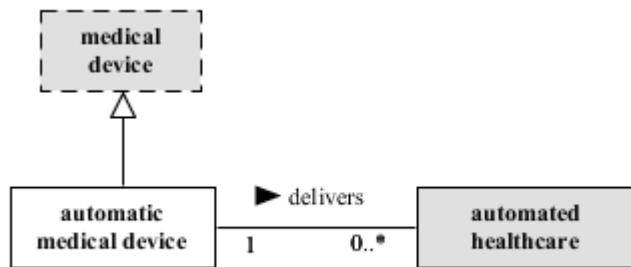


Figure 70 — Automatic medical device (UML representation)

8.6.3 Medicinal product

Term: medicinal product	
Synonyms: <i>medicine</i>	
Definition: any substance or combination of substances used for a human being with the intention of directly or indirectly improving or maintaining the health state of that human being	
NOTE	The source of this definition is [ISO/TR 25257:2009]
Specialization of	Generalization of
healthcare resource	

A model showing the associations of this concept is shown in Figure 71.

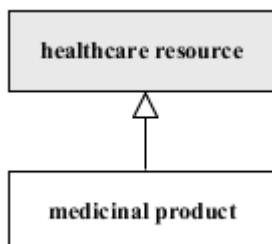


Figure 71 — Medicinal product (UML representation)

8.7 Adverse event

Term:	<i>adverse event</i>									
Definition: unintended event that may negatively influence a <i>healthcare process</i>										
NOTE 1 'Iatrogenesis' or 'iatrogeny' is a common cause of <i>adverse events</i> .										
NOTE 2 <i>Adverse events</i> can occur during appropriate <i>healthcare activities</i> .										
NOTE 3 Adverse events may cause harm										
EXAMPLES										
<ul style="list-style-type: none"> 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 <i>healthcare activity</i> can be an adverse event. A mishap during correctly performed <i>healthcare activity</i> may also be regarded as an adverse event 										
<table border="1"> <thead> <tr> <th>Specialization of</th> <th>Generalization of</th> </tr> </thead> <tbody> <tr> <td>unintended event</td> <td></td> </tr> </tbody> </table>		Specialization of	Generalization of	unintended event						
Specialization of	Generalization of									
unintended event										
<table border="1"> <thead> <tr> <th>Association from</th> <th>Association name</th> <th>Association to</th> </tr> </thead> <tbody> <tr> <td>0..* adverse event</td> <td>influences</td> <td>1..* healthcare process</td> </tr> <tr> <td>1 adverse event</td> <td>requires</td> <td>1 adverse event management</td> </tr> </tbody> </table>		Association from	Association name	Association to	0..* adverse event	influences	1..* healthcare process	1 adverse event	requires	1 adverse event management
Association from	Association name	Association to								
0..* adverse event	influences	1..* healthcare process								
1 adverse event	requires	1 adverse event management								

A model showing the associations of this concept is shown in Figure 72.

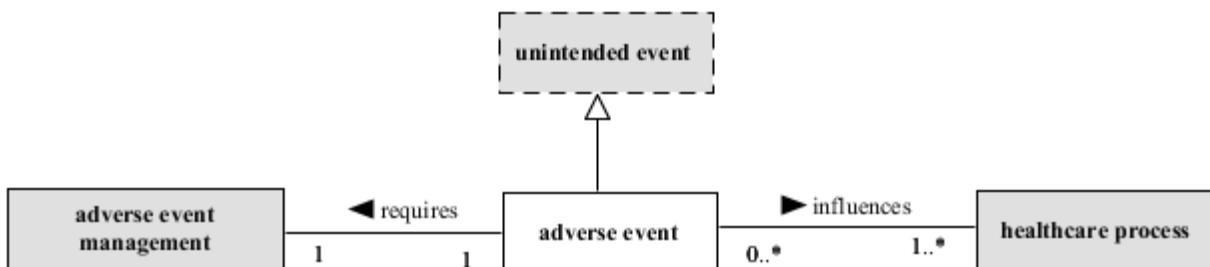


Figure 72 — Adverse event (UML representation)

8.8 Adverse event management

Term: <i>adverse event management</i>		
Definition: set of activities performed in response to an <i>adverse event</i>		
NOTE The purpose for <i>adverse event management</i> are usually two: one is to reverse the effect or minimize the consequences of the <i>adverse event</i> , another one is to prevent the kind of <i>adverse event</i> in the future.		
Association from	Association name	Association to
1 adverse event	requires	1 adverse event management

A model showing the associations of this concept is shown in Figure 73.

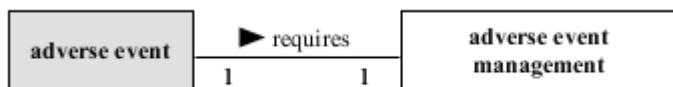


Figure 73 — Adverse event management (UML representation)

9. Concepts related to the use of clinical knowledge and decision support in continuity of care

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 74.

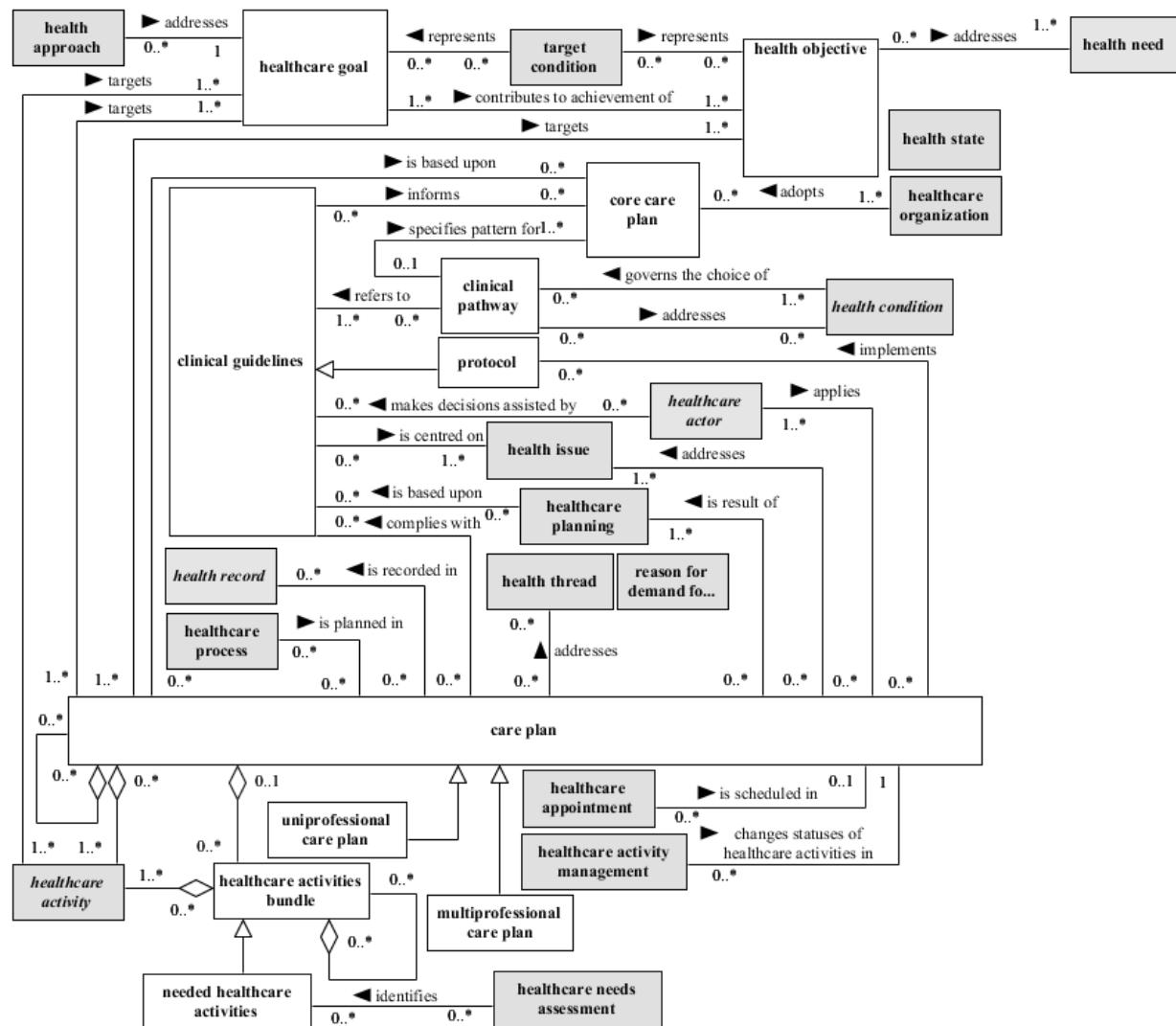


Figure 74 — Comprehensive UML diagram of concepts related to the use of clinical knowledge and decision support in continuity of care

9.2 Care plan

Term:	<i>care plan</i>		
Synonym:	healthcare plan		
Deprecated term:	programme of care		
Definition:	dynamic, personalized plan including identified <i>needed healthcare activities</i> , <i>health objectives</i> and <i>healthcare goals</i> , relating to one or more specified <i>health issues</i> in a <i>healthcare process</i>		
<p>NOTE 1 A <i>care plan</i> may be recorded in one or more <i>health records</i>.</p> <p>NOTE 2 A <i>care plan</i> could be subdivided from different perspectives by different constraints. One example is <i>uniprofessional care plan</i>, e.g. a nursing care plan with the constraint of only one specific health professional involved. Other examples of specific constraints for a <i>care plan</i> are:; <i>care plan</i> to address one <i>health issue</i>, one <i>health condition</i>, one <i>contact</i>, one <i>clinical process</i>, activities to be performed by one <i>healthcare provider</i>, one category of <i>healthcare professionals</i> etc.</p> <p>NOTE 3 <i>Care plans</i> are reviewed repeatedly during a <i>healthcare process</i>, each review based on a new healthcare needs assessment.</p> <p>NOTE 4 The <i>healthcare activities</i> in a <i>care plan</i> 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</p> <p>NOTE 5 In EN 13940-1:2007 programme of care was the preferred term for this concept.</p>			
EXAMPLE	A <i>care plan</i> for the diagnosis of retinopathy in diabetics by video-retinoscopy, which involves the GP and an ophthalmologist and implies specific mobile equipment (video-retinoscope) with a camera.		
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 guidelines
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
0..* healthcare activity management	changes statuses of healthcare activities in		1 care plan
0..* care plan	is recorded in		0..* health record

A model showing the associations of this concept is shown in Figure 75.

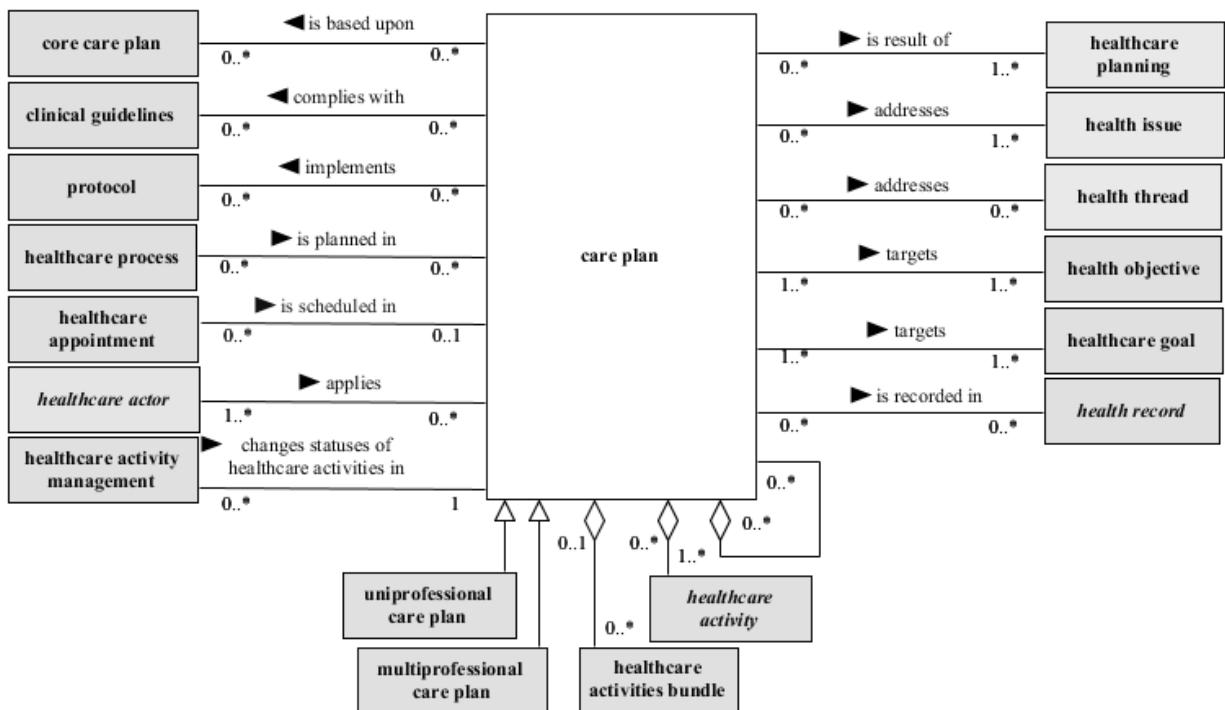


Figure 75 — Care plan (UML representation)

9.2.1 Core care plan

Term:	<i>core care plan</i>					
Synonym:	standardized care plan					
Definition:	Reusable content and structure for a <i>care plan</i> for a specified set of circumstances from which a <i>care plan</i> for a <i>subject of care</i> can be developed					
NOTE 1 A <i>core care plan</i> is usually based upon knowledge in <i>clinical guidelines</i> (including protocols).						
NOTE 2 <i>Core care plans</i> can be applied in care planning as a <i>clinical process management</i> method						
NOTE 3 A <i>core care plan</i> may include advanced formulated schemes for recommended <i>healthcare activities</i>						
Association from	Association name	Association to				
0..1 clinical pathway	specifies pattern for	1..* core care plan				
0..* clinical guidelines	informs	0..* core care plan				
1..* healthcare organization	adopts	0..* core care plan				
0..* care plan	is based upon	0..* core care plan				

A model showing the associations of this concept is shown in Figure 76.

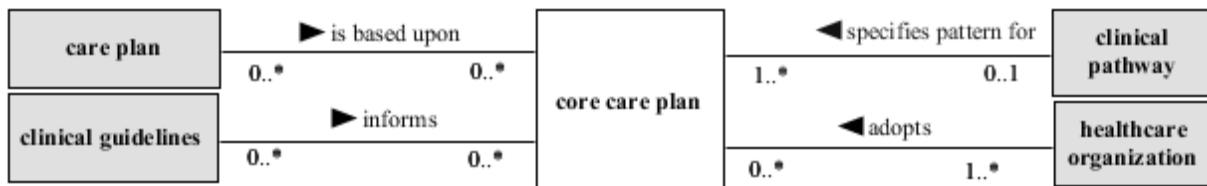


Figure 76 — Core care plan (UML representation)

9.2.2 Uniprofessional care plan

Term:	<i>uniprofessional care plan</i>
Synonym:	uniprofessional healthcare plan
Deprecated term:	care plan
Definition:	<i>care plan limited to those healthcare provider activities performed by healthcare professionals having the same healthcare professional entitlement</i>
NOTE	In EN 13940-1:2007 care plan was the preferred term for this concept.
EXAMPLE	A nursing care plan.
Specialization of	Generalization of
care plan	

A model showing the associations of this concept is shown in Figure 77.



Figure 77 — Uniprofessional care plan (UML representation)

9.2.3 Multi-professional care plan

Term:	<i>multi-professional care plan</i>
Synonym:	multi-professional healthcare plan, multi-disciplinary (MDT) care plan
Definition: <i>care plan</i> encompassing <i>healthcare provider activities</i> performed by <i>healthcare professionals</i> having different <i>healthcare professional entitlements</i>	
Specialization of	Generalization of
care plan	

A model showing the associations of this concept is shown in Figure 78.

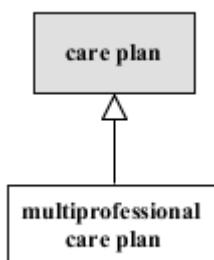


Figure 78 — Multi-professional care plan (UML representation)

9.3 Clinical guidelines

Term:	<i>clinical guidelines</i>	
Synonym:	care guideline	
Definition: set of systematically developed statements to assist the decisions made by <i>healthcare actors</i> about <i>healthcare activities</i> to be performed with regard to specified <i>health issues</i>		
<p>NOTE 1 <i>Clinical guidelines</i> are usually rather generic and they concern no actual <i>subject of care</i> in particular. While they generally reflect a broad statement of good practice, they may sometimes include multiple operational details.</p> <p>NOTE 2 <i>Clinical guidelines</i> should be structured and contain standard criteria and indicators for measurement.</p>		
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		
Specialization of	Generalization of	
	protocol	
Association from	Association name	Association to
0..* clinical guidelines	is centred on	1..* health issue
0..* clinical guidelines	informs	0..* core care plan
0..* clinical pathway	refers to	1..* clinical guidelines
0..* healthcare actor	makes decisions assisted by	0..* clinical guidelines
0..* healthcare planning	is based upon	0..* clinical guidelines
0..* care plan	complies with	0..* clinical guidelines

A model showing the associations of this concept is shown in Figure 79.

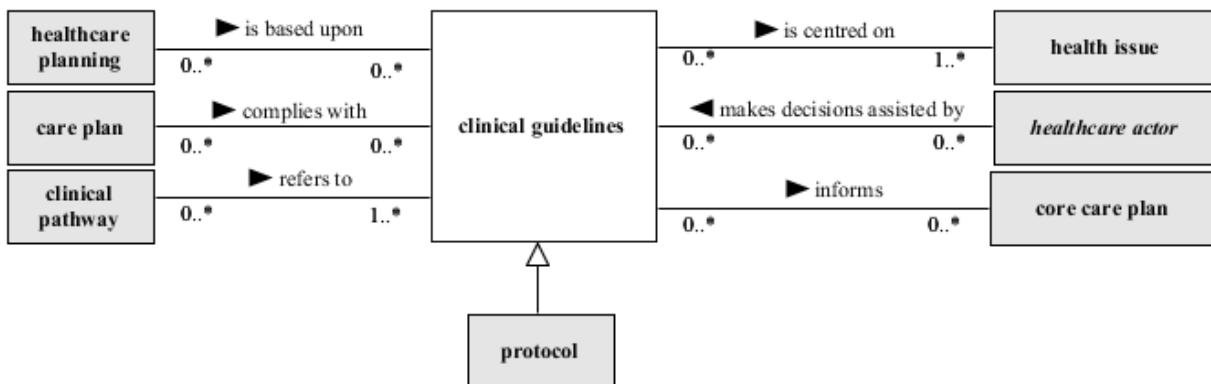


Figure 79 — Clinical guidelines (UML representation)

9.4 Protocol

Term:	<i>protocol</i>	
Definition: <i>clinical guidelines</i> customized for operational use		
NOTE 1 A <i>protocol</i> is more precise than a <i>clinical guideline</i> .		
NOTE 2 <i>Protocols</i> are often presented in a formal manner with respect to the expected behaviours and roles of <i>healthcare actors</i> .		
EXAMPLES A <i>protocol</i> for a heart failure in an emergency department, a <i>protocol</i> for treatment and follow-up of urinary infections in children in a health centre.		
Specialization of	Generalization of	
clinical guidelines		
Association from	Association name	Association to
1..* care plan	implements	0..* protocol

A model showing the associations of this concept is shown in Figure 80.

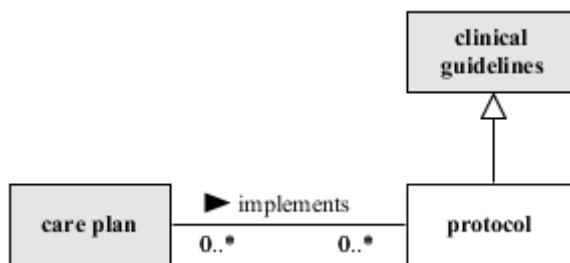


Figure 80 — Protocol (UML representation)

9.5 Clinical pathway

Term:	<i>clinical pathway</i>	
Synonym:	care pathway, care map, pathways of care	
Definition: structured pattern for the healthcare activities in a <i>core care plan</i> to be adopted in <i>care plans</i> for <i>subjects of care</i> having similar <i>health conditions</i> with a predictable clinical course		
NOTE 1 The concept <i>clinical pathway</i> includes subtypes e.g. 'integrated care pathways', 'multidisciplinary pathways of care', 'collaborative care pathways'.		
NOTE 2 <i>Clinical pathways</i> are designed to support <i>healthcare administration</i> and <i>healthcare resource management</i> . They provide detailed guidance for each stage in the management of a patient (treatments, interventions etc.).		
Association from	Association name	Association to
0..* clinical pathway	refers to	1..* clinical guidelines
0..1 clinical pathway	specifies pattern for	1..* core care plan
0..* clinical pathway	addresses	1..* health condition
1..* health condition	governs the choice of	0..* clinical pathway

A model showing the associations of this concept is shown in Figure 81.

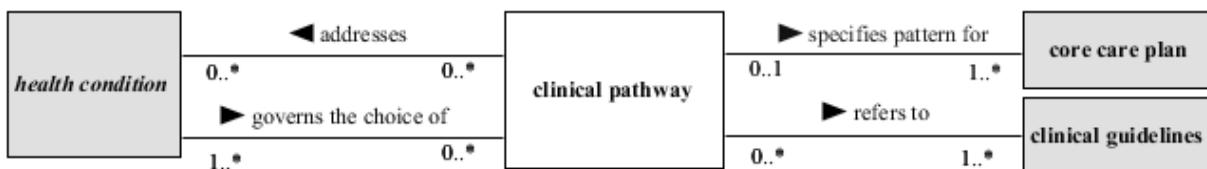


Figure 81 — Clinical pathway (UML representation)

9.6 Health objective

Term:	<i>health objective</i>	
Synonym:	intended outcome	
Definition: desired ultimate achievement of a <i>healthcare process</i> addressing <i>health needs</i>		
NOTE A <i>health objective</i> could be expressed as one or several <i>target conditions to be reached within a specified date and time</i> .		
EXAMPLES		
	<ul style="list-style-type: none"> • To increase the survival of a <i>subject of care</i> with breast cancer in a breast cancer screening programme. • To reduce a <i>subject of care</i> risk of morbidity and mortality from tobacco related diseases in a smoking cessation programme. • To decrease a <i>subject of care</i> risk of secondary effects to diabetes 	
Association from	Association name	Association to
0..* health objective	addresses	1..* health need
1..* healthcare goal	contributes to achievement of	1..* health objective
0..* target condition	represents	0..* health objective
1..* care plan	targets	1..* health objective

A model showing the associations of this concept is shown in Figure 82.

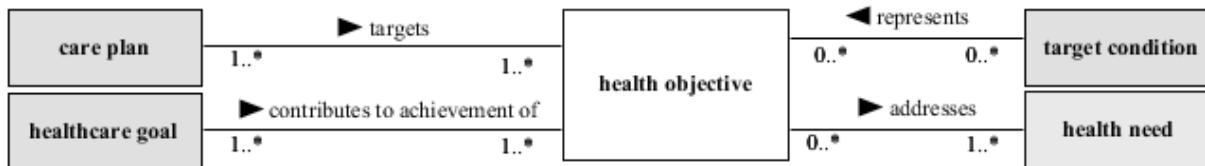


Figure 82 — Health objective (UML representation)

9.7 Healthcare goal

Term:	<i>healthcare goal</i>	
Definition: desired achievement of one or more <i>healthcare activities</i> in a <i>care plan</i> , considered as an intermediate operational step to reach a specific <i>health objective</i>		
NOTE A <i>healthcare goal</i> could be expressed as one or several <i>target conditions to be reached within a specified date and time</i> .		
EXAMPLES		
<ul style="list-style-type: none"> To increase the <i>subject of care's</i> adherence to the treatment in a hypertension programme. To stabilise the <i>subject of care's</i> systolic and diastolic pressure in a hypertension programme. To increase the <i>subject of care's</i> knowledge of their disease through an educational programme for diabetics. 		
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

A model showing the associations of this concept is shown in Figure 83.

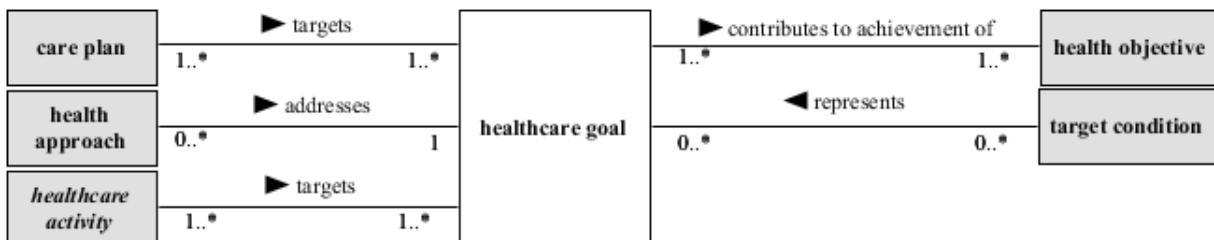


Figure 83 — Healthcare goal (UML representation)

9.8 Healthcare activities bundle

Term: <i>healthcare activities bundle</i>	
Definition: set of <i>healthcare activities</i> in the context of one or more <i>care plans</i>	
EXAMPLE All <i>healthcare activities</i> provided to a <i>subject of care</i> in preision of, during and in the aftermath of a planned surgical operation, in relation to that operation.	
Specialization of	Generalization of
	needed healthcare activities
Component of	Aggregation of
0..* healthcare activities bundle	0..* healthcare activities bundle
0..1 care plan	1..* healthcare activity

A model showing the associations of this concept is shown in Figure 84.

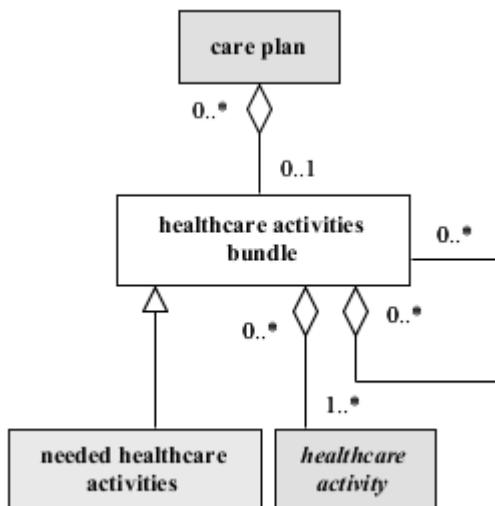


Figure 84 — Healthcare activities bundle (UML representation)

9.8.1 Needed healthcare activities

Term:	<i>needed healthcare activities</i>	
Synonyms:	needed care activities, healthcare need, care need	
Definition: <i>healthcare activities needed to address specific health needs</i>		
NOTE 1 <i>Needed healthcare activities</i> are the <i>healthcare activities</i> that by <i>healthcare professionals</i> are assessed motivated/indicated by <i>health needs</i> .		
NOTE 2 <i>Needed healthcare activities</i> are the outcome of <i>healthcare needs assessments</i> performed by <i>healthcare professionals</i> . <i>Needed healthcare activities</i> can be identified by any mandated <i>healthcare professional</i> performing <i>healthcare needs assessment</i> for a <i>subject of care</i> .		
NOTE 3 <i>Needed healthcare activities</i> are managed in a <i>care plan</i> .		
Specialization of	Generalization of	
healthcare activities bundle		
Association from	Association name	Association to
0..* healthcare needs assessment	identifies	0..* needed healthcare activities

A model showing the associations of this concept is shown in Figure 85.

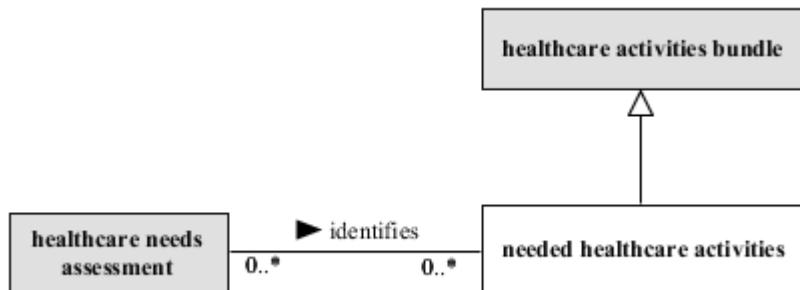


Figure 85 — Needed healthcare activities (UML representation)

10. Concepts related to activity

10.1 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 86 and 87.

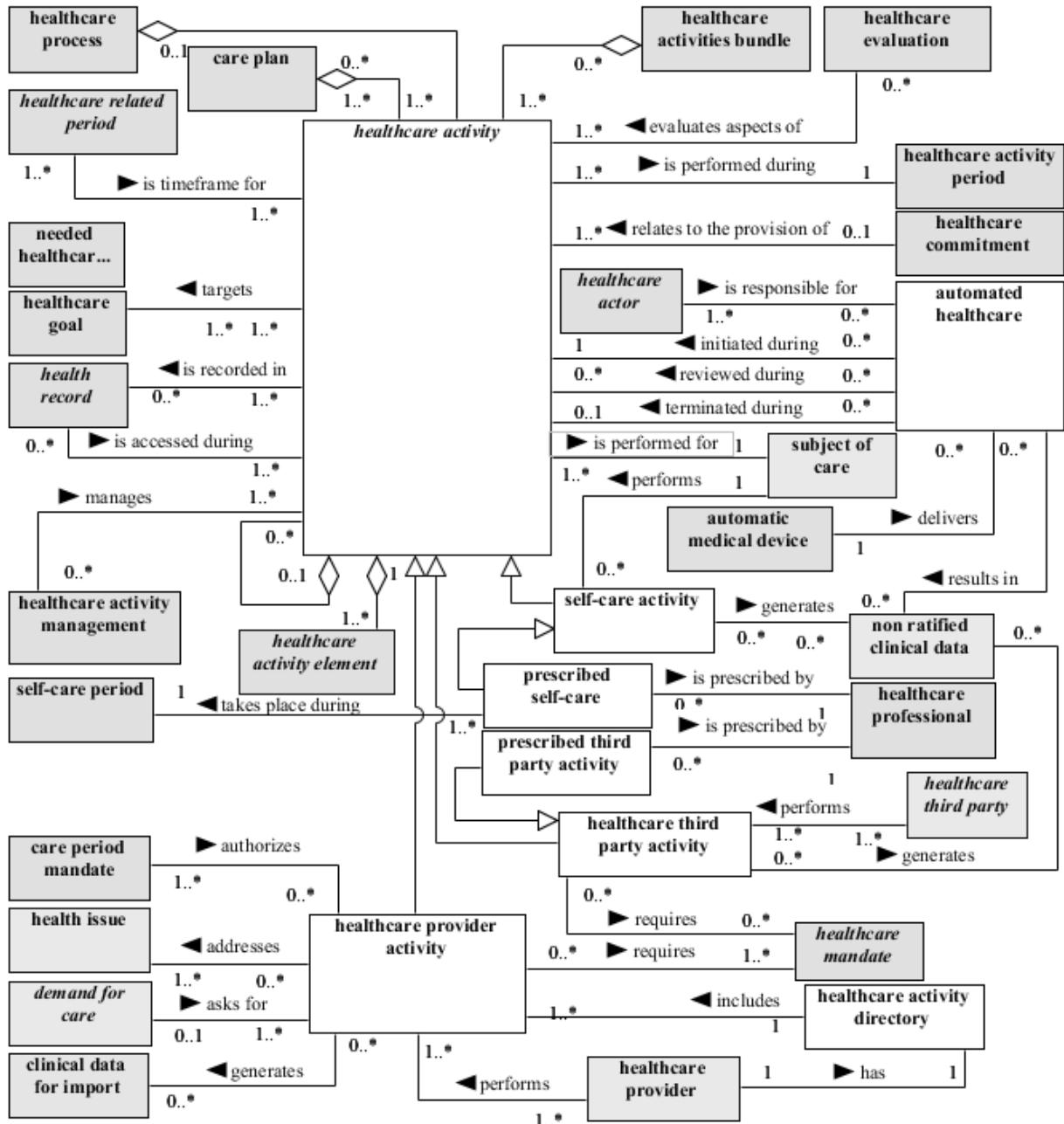


Figure 86 — Comprehensive UML diagram of concepts related to activity

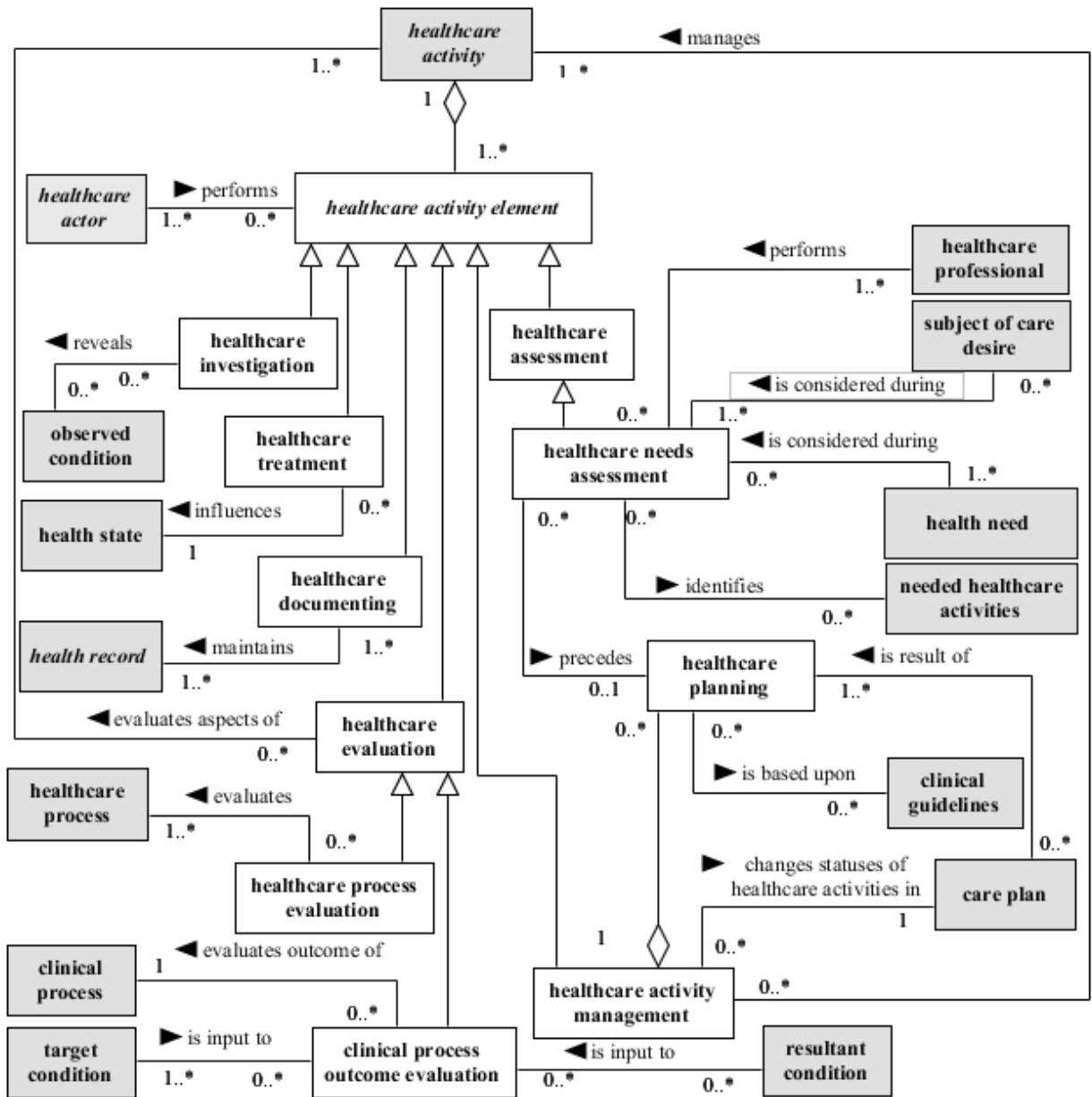


Figure 87 — Comprehensive UML diagram of concepts related to activity elements

10.2 Healthcare activity

Term: <i>healthcare activity</i>			
Definition: activity performed for a <i>subject of care</i> with the intention of directly or indirectly improving or maintaining the <i>health state</i> of that <i>subject of care</i>			
NOTE 1 Each specialisation of this concept represents <i>healthcare activities</i> performed by a specialisation of healthcare actor.			
NOTE 2 Different types of elements like e.g. <i>healthcare investigation</i> or <i>healthcare treatment</i> may be performed during a healthcare activity.			
NOTE 3 See the concepts <i>healthcare provider activity</i> , <i>self-care activity</i> , <i>healthcare third party activity</i> and <i>automated healthcare</i> when it comes to the recording of information that are the result of <i>healthcare activities</i> (e.g. ratified observations).			
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..*	
0..1	healthcare activity	0..*	
Association from		Association name	
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
0..1	healthcare commitment	relates to the provision of	1..* healthcare activity
1..*	health related period	is timeframe for	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

A model showing the associations of this concept is shown in Figure 88.

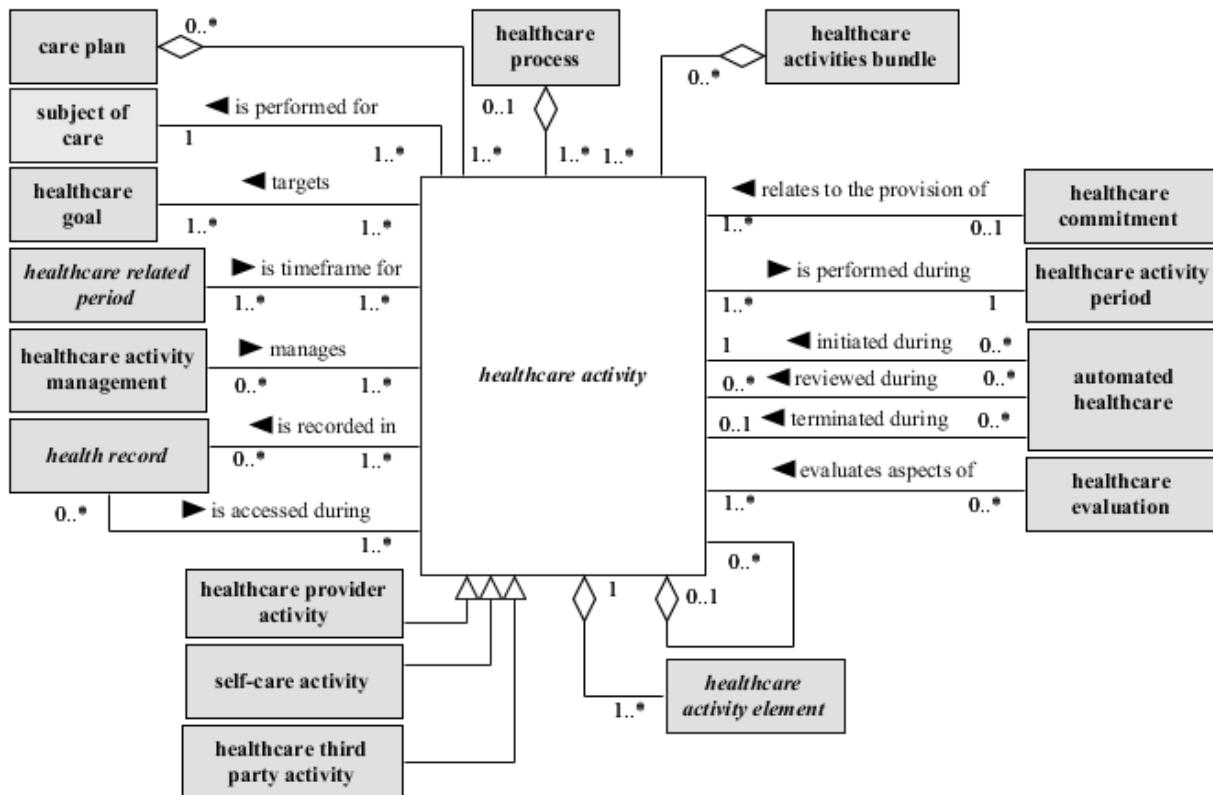


Figure 88 — Healthcare activity (UML representation)

10.2.1 Healthcare activity element

Term:	<i>healthcare activity element</i>	
Synonyms:		
Definition:	element of <i>healthcare activity</i> that addresses one type of purpose	
Specialization of	Generalization of	
	healthcare investigation	
	healthcare assessment	
	healthcare treatment	
	healthcare evaluation	
	healthcare documenting	
	healthcare activity management	
Component of	Aggregation of	
1 healthcare activity		
Association from	Association name	Association to
1..* healthcare actor	performs	0..* healthcare activity element

A model showing the associations of this concept is shown in Figure 89.

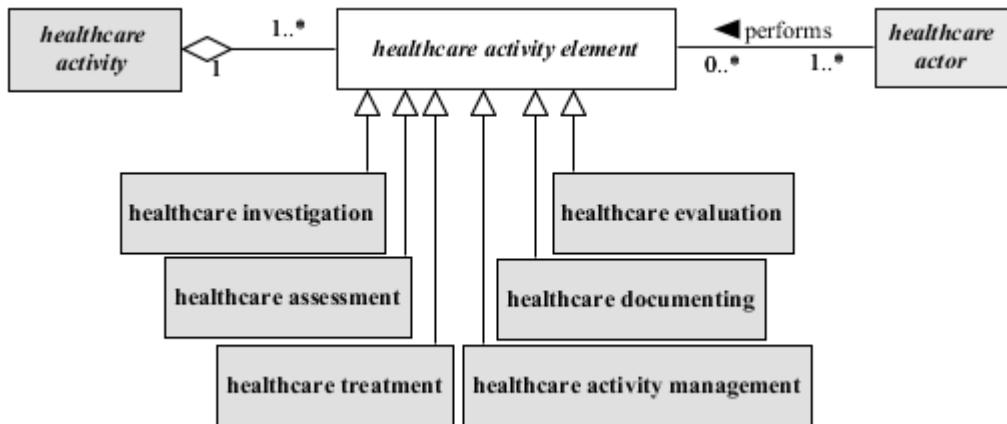


Figure 89 — Healthcare activity element (UML representation)

10.2.1.1. Healthcare treatment

Term:	<i>healthcare treatment</i>	
Definition: <i>healthcare activity element intended to directly improve or maintain the <i>health state</i> of a subject of care</i>		
NOTE 1 The treatment of a <i>subject of care's health state</i> , based on that <i>subject of care's health conditions</i> , is a part of the <i>clinical process</i> considered from a therapeutic perspective.		
NOTE 2 <i>Healthcare treatment</i> is intended to contribute to fulfilling an assessed health need.		
NOTE 3 Prevention is a type of <i>healthcare treatment</i> where the risk of a <i>health condition</i> is treated		
NOTE 4 <i>Healthcare treatment</i> includes all types of activities that intend to influence the <i>health state</i> including e.g. rehabilitation, palliative care, education of subjects of care, caring etc.		
Specialization of	Generalization of	
healthcare activity element		
Association from	Association name	Association to
0..* Healthcare treatment	is influencing	1 health state

A model showing the associations of this concept is shown in Figure 90.

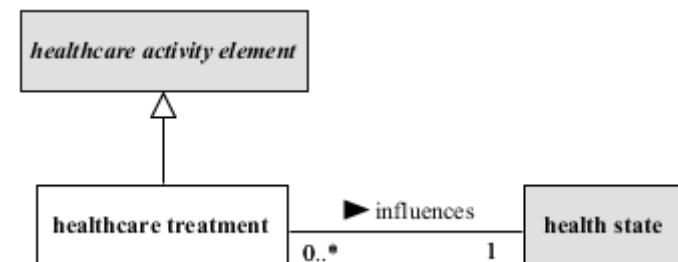


Figure 90 — Healthcare treatment (UML representation)

10.2.1.2. Healthcare investigation

Term: <i>healthcare investigation</i>		
Definition: <i>healthcare activity element</i> with the intention to clarify one or more <i>health conditions</i> of a <i>subject of care</i>		
NOTE 1 <i>Healthcare investigations</i> add and improve information about aspects of the <i>health state</i> of a <i>subject of care</i>		
Specialization of	Generalization of	
healthcare activity element		
Association from	Association name	Association to
0..* healthcare investigation	reveals	0..* health condition

A model showing the associations of this concept is shown in Figure 91.

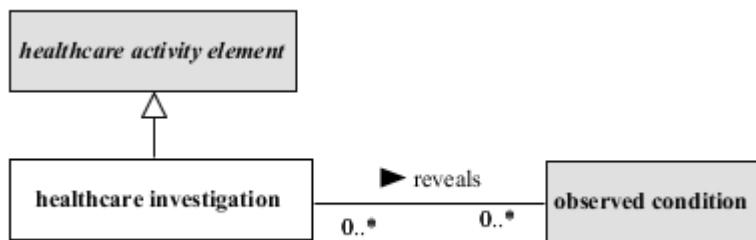


Figure 91 — Healthcare investigation (UML representation)

10.2.1.3. Healthcare activity management

Term:	<i>healthcare activity management</i>		
Definition:	<i>healthcare activity element</i> where the statuses of <i>healthcare activities</i> in a <i>care plan</i> are changed		
NOTE Examples of statuses of <i>healthcare activities</i> to be changed by <i>healthcare activity management</i> are; planned, scheduled, resource allocated, ongoing, performed / finished, evaluated.			
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	
1..* healthcare activity management	changes statuses of healthcare activities in	1..* care plan	

A model showing the associations of this concept is shown in Figure 92.

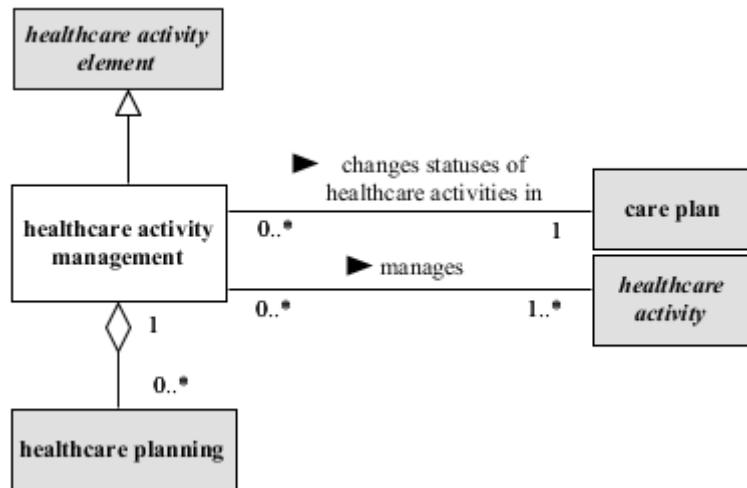


Figure 92 — Healthcare activity management (UML representation)

10.2.1.4. Healthcare assessment

Term:	<i>healthcare assessment</i>
Definition: <i>healthcare activity element</i> where an opinion related to <i>health conditions</i> and/or <i>healthcare activities</i> is formed	
Specialization of	Generalization of
healthcare activity element	healthcare needs assessment

A model showing the associations of this concept is shown in Figure 93.

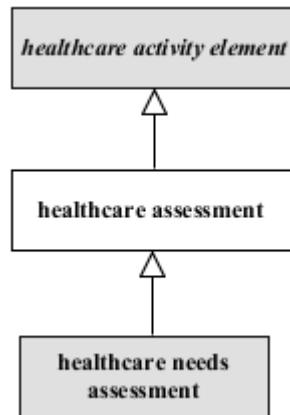


Figure 93 — Healthcare assessment (UML representation)

10.2.1.5. Healthcare evaluation

Term:	<i>healthcare evaluation</i>			
Definition: <i>healthcare activity element</i> where aspects of at least one <i>healthcare activity</i> is evaluated				
NOTE 1 <i>Healthcare evaluation</i> may be performed by all kinds of <i>healthcare actors</i> , including the <i>subject of care</i> .				
NOTE 2 See also <i>clinical process outcome evaluation</i> .				
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		

A model showing the associations of this concept is shown in Figure 94.

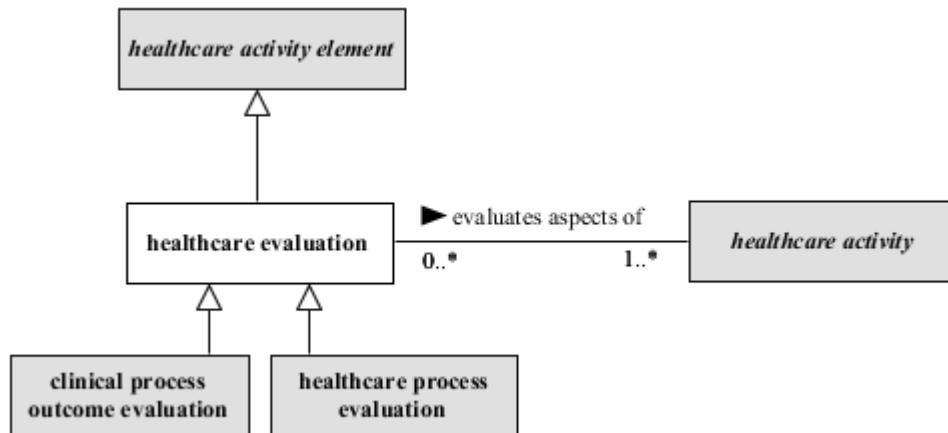


Figure 94 — Healthcare evaluation (UML representation)

10.2.1.6. Healthcare documenting

Term:	<i>healthcare documenting</i>	
Synonym:		
Definition:	<i>healthcare activity element</i> where <i>health records</i> are maintained	
Specialization of	Generalization of	
healthcare activity element		
Association from	Association name	Association to
1..* healthcare documenting	maintains	1..* health record

A model showing the associations of this concept is shown in Figure 95.

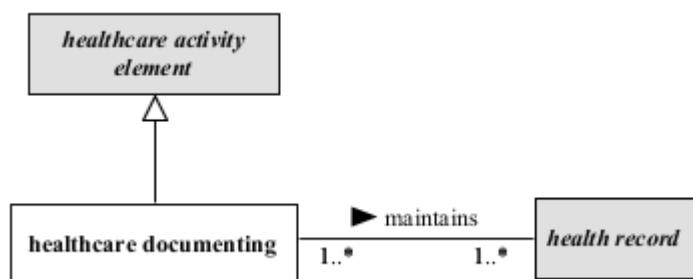


Figure 95 — Healthcare documenting (UML representation)

10.2.2 Healthcare provider activity

Term:	<i>healthcare provider activity</i>					
Definition:	<i>healthcare activity performed by a healthcare provider</i>					
NOTE 1 A <i>healthcare provider activity</i> can be performed in relation to several <i>healthcare activity period elements</i> of the same <i>healthcare activity period</i> .						
NOTE 2 When the <i>healthcare provider</i> is a <i>healthcare organization</i> , the activities are performed by the <i>healthcare personnel</i> of that <i>healthcare organization</i> .						
EXAMPLES	<ul style="list-style-type: none"> • Acts, procedures, interventions. 					
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..*	clinical data for import			
1..* healthcare provider	performs	1..*	healthcare provider activity			
1..* care period mandate	authorizes	0..*	healthcare provider activity			
0..1 demand for care	asks for	1..*	healthcare provider activity			
0..* healthcare provider activity	requires	1..*	healthcare mandate			
1 healthcare activity directory	includes	1..*	healthcare provider activity			

A model showing the associations of this concept is shown in Figure 96.

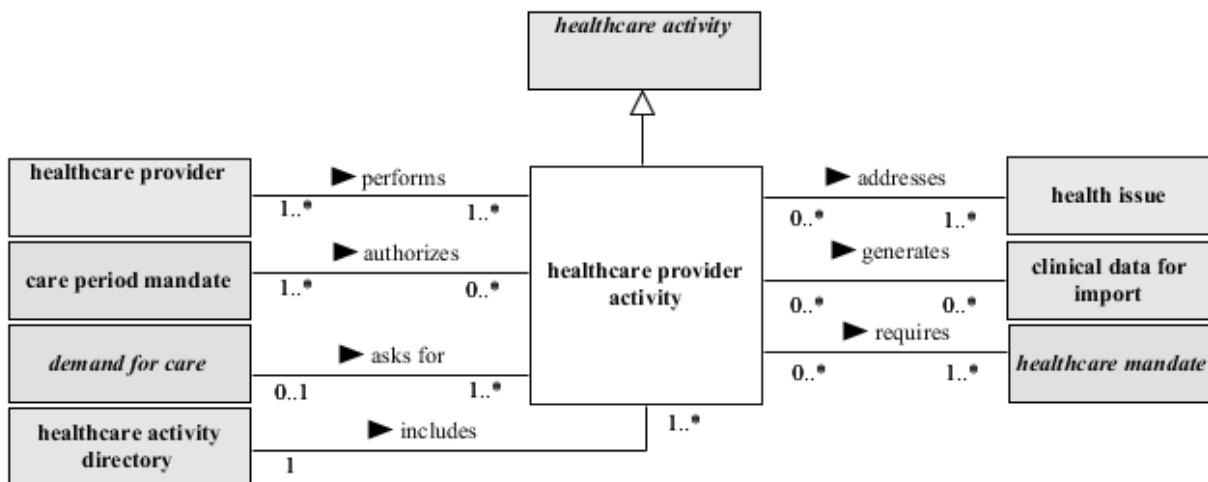


Figure 96 — Healthcare provider activity (UML representation)

10.2.3 Healthcare needs assessment

Term:	<i>healthcare needs assessment</i>		
Definition:	<i>healthcare assessment</i> during which a <i>healthcare professional</i> considers a <i>subject of care's health needs</i> and determines the <i>needed healthcare activities</i>		
<p>NOTE 1 A <i>healthcare needs assessment</i> precedes <i>healthcare planning</i></p> <p>NOTE 2 <i>Healthcare needs assessments</i> should be performed in a dialogue with the <i>subject of care</i>. The responsibility for a <i>healthcare needs assessment</i> is held by a <i>healthcare professional</i>.</p> <p>NOTE 3 The <i>subjects of care</i> interact with <i>healthcare professionals</i> in <i>healthcare needs assessments</i> and also describe their opinions on which <i>healthcare activities</i> should be asked for in a <i>demand for care</i>.</p>			
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
0..* healthcare professional	performs	0..*	healthcare needs assessment
0..* healthcare needs assessment	identifies	0..*	needed healthcare activities
1..* health need	is considered during	0..*	healthcare needs assessment

A model showing the associations of this concept is shown in Figure 97.

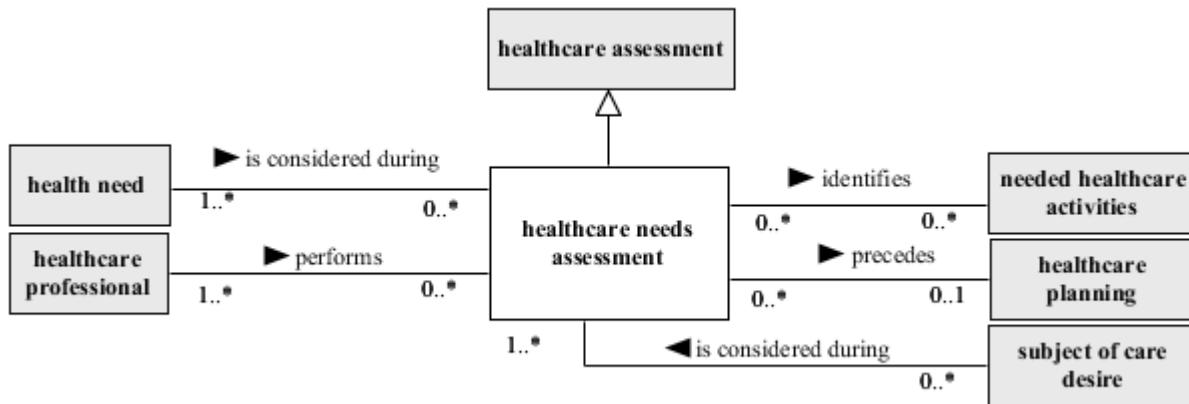


Figure 97 — Healthcare needs assessment (UML representation)

10.2.3.1. Healthcare planning

Term:	<i>healthcare planning</i>	
Synonyms:	<i>care planning</i>	
Definition: element of <i>healthcare activity management</i> where a <i>care plan</i> is created or modified		
Component of	Aggregation of	
1 healthcare activity management		
Specialization of	Generalization of	
Association from	Association name	Association to
0..* healthcare planning	is based upon	0..* clinical guidelines
0..* care plan	is result of	1..* healthcare planning
0..* healthcare needs assessment	precedes	0..1 healthcare planning

A model showing the associations of this concept is shown in Figure 98.

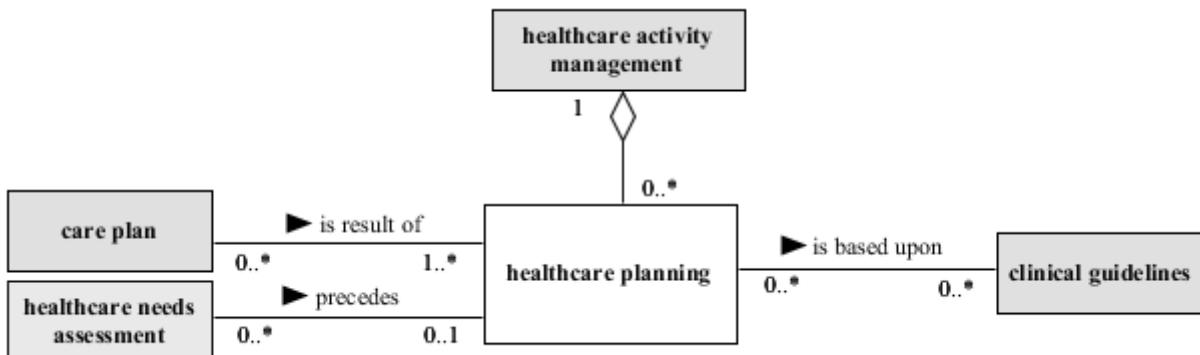


Figure 98 — Healthcare planning (UML representation)

10.2.3.2. Healthcare process evaluation

Term:	<i>healthcare process evaluation</i>	
Definition: <i>healthcare evaluation</i> where <i>healthcare processes</i> are systematically assessed against requirements		
<p>NOTE 1 The outputs of <i>clinical processes</i> are evaluated in a <i>clinical process outcome evaluation</i>.</p> <p>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 e.g. <i>target conditions</i>, goals for resource consumption, compliance to guidelines etc. The expectations can be represented by the perceptions of the outcomes from each of the involved actor's perspective (i.e. <i>subject of care</i> and <i>healthcare professionals</i>).</p>		
Specialization of	Generalization of	
healthcare evaluation		
Association from	Association name	Association to
1..* healthcare process	is evaluated in	0..* healthcare process evaluation

A model showing the associations of this concept is shown in Figure 99.

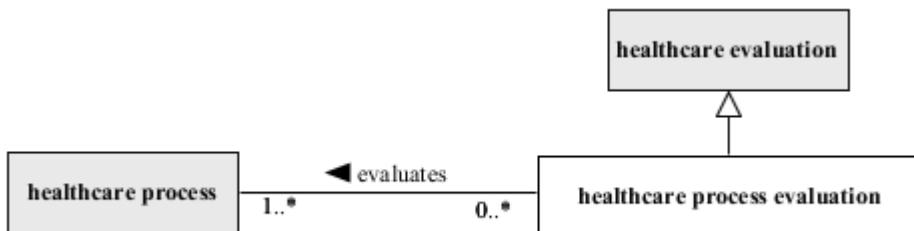


Figure 99 — Healthcare process evaluation (UML representation)

10.2.3.3. Clinical process outcome evaluation

Term:	<i>clinical process outcome evaluation</i>	
Definition: <i>healthcare evaluation</i> where the effects of a <i>clinical process</i> on the <i>health state</i> of a <i>subject of care</i> are assessed against the <i>target condition</i> and/or a <i>health condition</i> representing the <i>input health state</i>		
NOTE 1 In an evaluation of the <i>clinical process</i> the <i>resultant condition</i> is compared to the <i>target condition</i> . The <i>subject of care</i> and <i>healthcare professionals</i> are the main contributors to a <i>clinical process outcome evaluation</i> .		
NOTE 2 The <i>target condition</i> represents a requirement for the <i>clinical process</i> .		
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
1..* resultant condition	is input to	0..* clinical process outcome evaluation

A model showing the associations of this concept is shown in Figure 100.

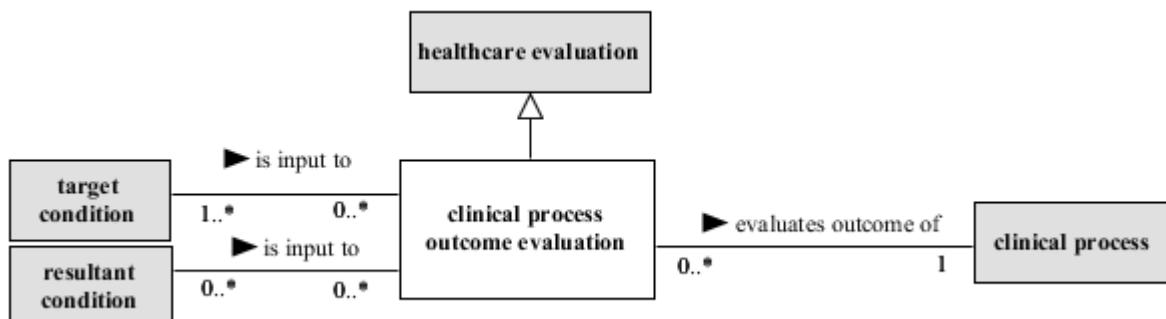


Figure 100 — Clinical process outcome evaluation (UML representation)

10.2.4 Self-care activity

Term:	<i>self-care activity</i>	
Deprecated term:	health self-care activity	
Definition: <i>healthcare activity performed by the subject of care</i>		
NOTE 1 There are two kinds of <i>self-care activities</i> that should be distinguished. a) <i>Prescribed self-care</i> that is included in a <i>care plan</i> and the documentation is included in a <i>professional health record</i> 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.	
Specialization of	Generalization of	
healthcare activity	prescribed self-care	
Association from	Association name	Association to
0..* self-care activity	generates	0..* non ratified clinical data
1 subject of care	performs	0..* self-care activity

A model showing the associations of this concept is shown in Figure 101.

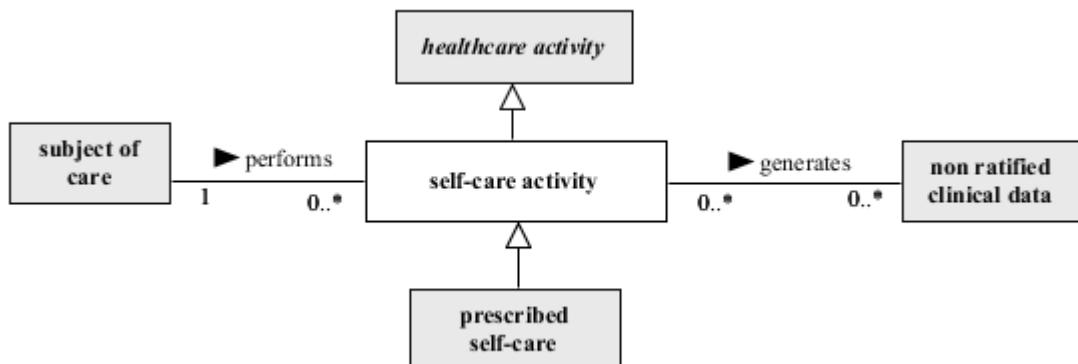


Figure 101 — Self-care activity (UML representation)

10.2.5 Prescribed self-care

Term:	<i>prescribed self-care</i>		
Definition:	<i>self-care activity prescribed by a healthcare professional</i>		
Specialization of self-care activity	Generalization of		
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

A model showing the associations of this concept is shown in Figure 102.

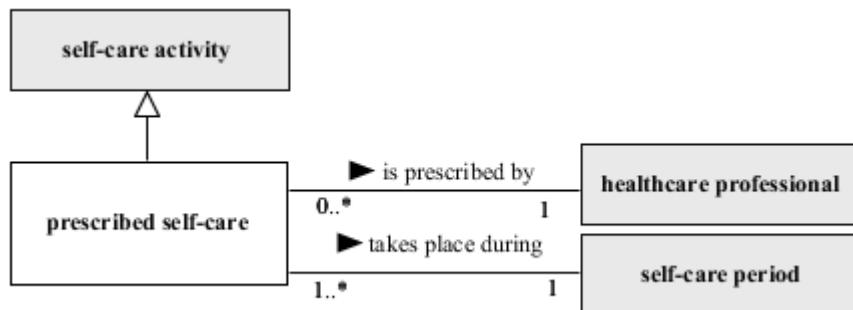


Figure 102 — Prescribed self-care (UML representation)

10.2.6 Healthcare third party activity

Term: <i>healthcare third party activity</i>												
Synonym: healthcare contributing activity												
Definition: <i>healthcare activity performed by a healthcare third party</i>												
<p>NOTE There are two kinds of <i>healthcare third party activities</i> that should be distinguished.</p> <ul style="list-style-type: none"> a) <i>Prescribed contributing care</i> that is included in a <i>care plan</i> and the documentation is included in an <i>health record</i>. b) <i>Healthcare third party activities</i> that are not prescribed. 												
NOTE 2 In EN 13940-1:2007 healthcare contributing activity was the preferred term for this concept.												
EXAMPLES The <i>healthcare treatment</i> of a bedsores by a <i>subject of care's</i> relation, <i>healthcare treatment</i> on advice by a chemist.												
<table border="1"> <thead> <tr> <th>Specialization of</th> <th>Generalization of</th> </tr> </thead> <tbody> <tr> <td>healthcare activity</td> <td>prescribed third party activity</td> </tr> </tbody> </table>	Specialization of	Generalization of	healthcare activity	prescribed third party activity								
Specialization of	Generalization of											
healthcare activity	prescribed third party activity											
<table border="1"> <thead> <tr> <th>Association from</th> <th>Association name</th> <th>Association to</th> </tr> </thead> <tbody> <tr> <td>0..*</td> <td>generates</td> <td>0..* non ratified clinical data</td> </tr> <tr> <td>0..*</td> <td>requires</td> <td>0..* healthcare mandate</td> </tr> <tr> <td>1..*</td> <td>performs</td> <td>1..* healthcare third party activity</td> </tr> </tbody> </table>	Association from	Association name	Association to	0..*	generates	0..* non ratified clinical data	0..*	requires	0..* healthcare mandate	1..*	performs	1..* healthcare third party activity
Association from	Association name	Association to										
0..*	generates	0..* non ratified clinical data										
0..*	requires	0..* healthcare mandate										
1..*	performs	1..* healthcare third party activity										

A model showing the associations of this concept is shown in Figure 103.

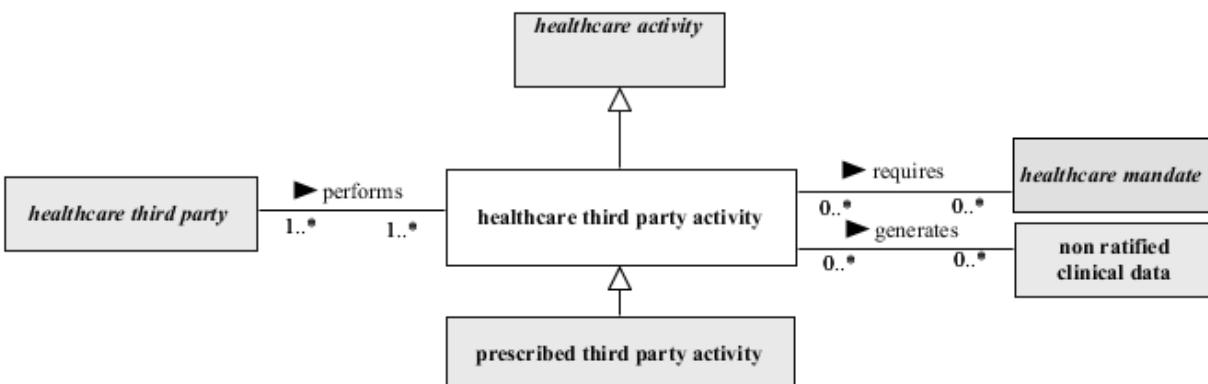


Figure 103 — Healthcare third party activity (UML representation)

10.2.6.1. Prescribed third party activity

Term:	<i>prescribed third party activity</i>	
Definition:	<i>healthcare third party activity</i> prescribed by a <i>healthcare professional</i>	
Specialization of		Generalization of
healthcare third party activity		
Association from	Association name	Association to
1 prescribed third party activity	is prescribed by	1 healthcare professional

A model showing the associations of this concept is shown in Figure 104.

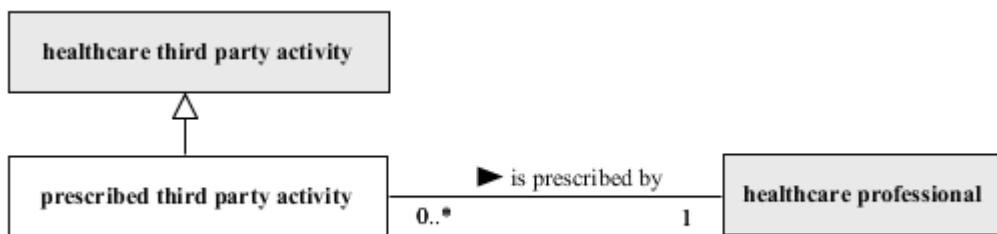


Figure 104 — Prescribed healthcare third party (UML representation)

10.2.7 Automated healthcare

Term: automated healthcare				
Definition: method of delivering healthcare initiated by a responsible <i>healthcare actor</i> and thereafter delivered automatically by an <i>automatic medical device</i>				
<p>NOTE <i>Automated healthcare</i> is not a <i>healthcare activity</i> in its own right since the <i>automatic medical device</i> doesn't have the capacity to be responsible. It is the <i>healthcare actor</i> who initiates and reviews the <i>automated healthcare</i> that is responsible for safe use of the <i>automatic medical device</i>.</p>				
EXAMPLE Activities performed by the machine during a long term Electrocardiography ("Holter recording") programme, implanted cardiac defibrillator.				
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 clinical data	
1..* healthcare actor	is responsible for	0..*	automated healthcare	
1 automatic medical device	delivers	0..*	automated healthcare	

A model showing the associations of this concept is shown in Figure 105.

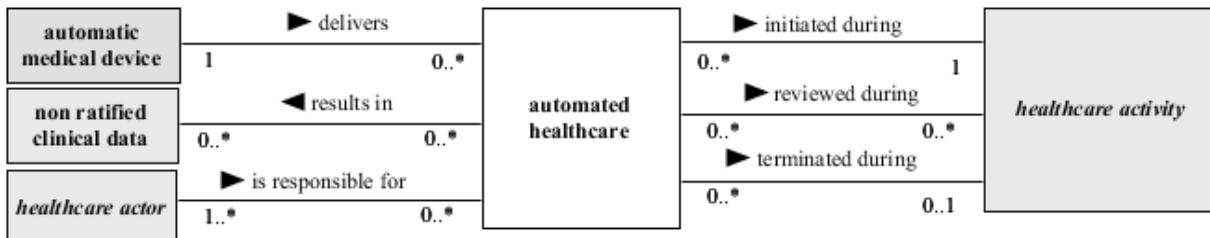


Figure 105 — Automated healthcare (UML representation)

10.3 Healthcare activity directory

Term:	<i>healthcare activity directory</i>					
Definition: directory of the types of <i>healthcare activities</i> that a given <i>healthcare provider</i> is able to provide						
NOTE 1 The <i>healthcare activity directory</i> includes those <i>healthcare activities</i> that the healthcare personnel of a <i>healthcare provider</i> is able to perform, not those that are actually available at the time of <i>healthcare delivery</i> . The ability to perform a <i>healthcare activity</i> implies that the <i>healthcare provider</i> has the necessary resources.						
NOTE 2 The <i>healthcare activity directory</i> is related to the management of <i>healthcare processes</i>						
NOTE 3 <i>Healthcare providers</i> may also have a directory of the services they offer. This directory includes the services that can be delivered by <i>healthcare processes</i> using the <i>healthcare activities</i> included in the <i>healthcare activity directory</i> .						
Association from	Association name	Association to				
1 healthcare activity directory	includes	1..*	healthcare provider activity			
1 healthcare provider	has	1	healthcare activity directory			

A model showing the associations of this concept is shown in Figure 106.

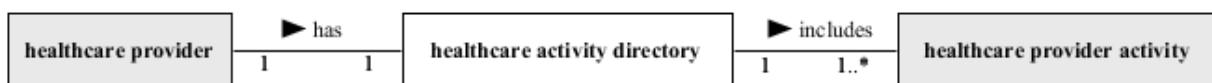


Figure 106 — Healthcare activity directory (UML representation)

11. Concepts related to responsibility in Continuity of Care

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 107.

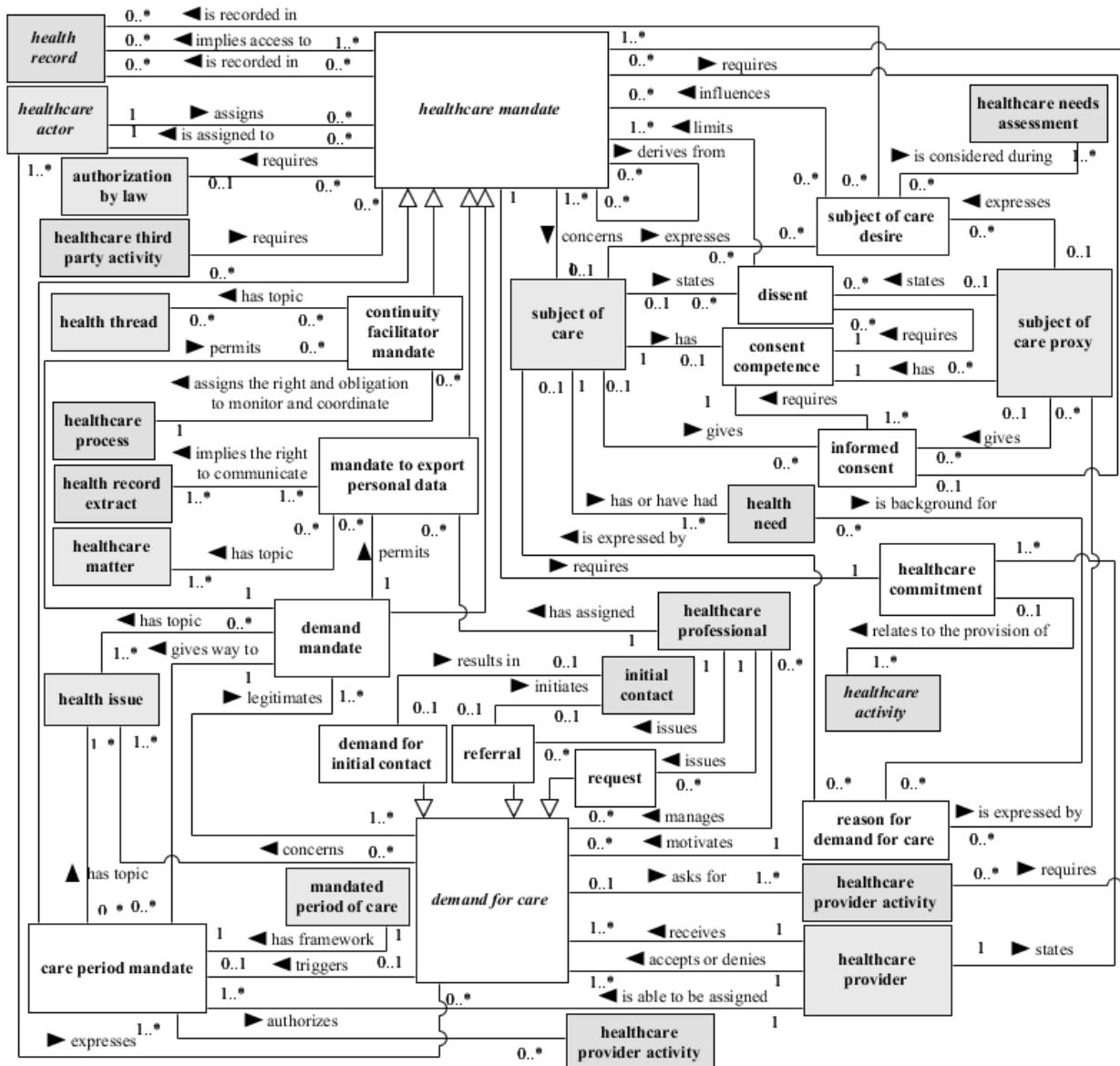


Figure 107 — Comprehensive UML diagram of the concepts related to responsibility in continuity of care

11.2 Demand for care

Term: <i>demand for care</i>
Synonym: demand for healthcare
Definition: demand expressed by a <i>healthcare actor</i> that <i>healthcare activities</i> be provided by a <i>healthcare provider</i>
NOTE 1 A <i>demand for care</i> may be expressed either by the <i>subject of care</i> or on their behalf.
NOTE 2 A <i>healthcare provider</i> may accept or decline a <i>demand for care</i> .
NOTE 3 A demand for care could result in a healthcare assessment concluding that no other activity elements (as investigations and/or treatments) should be performed.
EXAMPLES
<ul style="list-style-type: none"> • An emergency call to a GP for a home visit at night. • A <i>request</i> for an appointment at a cardiology outpatient department. • A <i>request</i> for the intervention of a community nurse.

Specialization of	Generalization of
	referral
	request
	demand for initial contact

Association from	Association name	Association to
1..* demand for care	legitimizes	1..* demand mandate
0..1 demand for care	asks for	1..* healthcare provider activity
0..* demand for care	concerns	1..* health issue
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

A model showing the associations of this concept is shown in Figure 108.

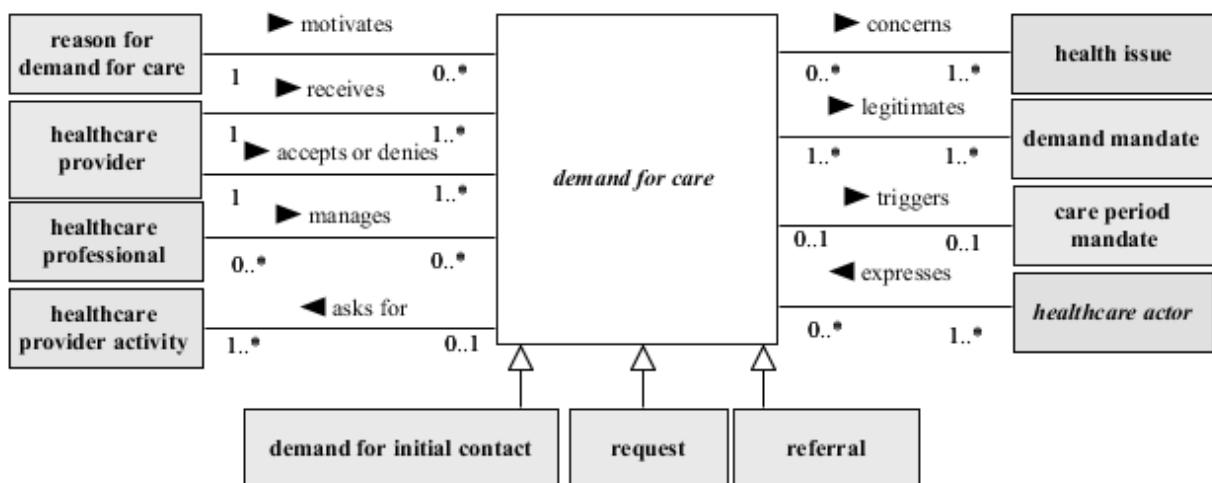


Figure 108 — Demand for care (UML representation)

11.2.1 Demand for initial contact

Term:	demand for initial contact	
Definition: first <i>demand for care</i> concerning one or more specific <i>health issues</i> to be assessed by a <i>healthcare provider</i>		
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

A model showing the associations of this concept is shown in Figure 109.

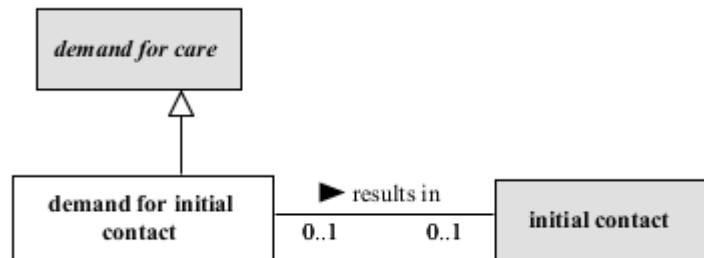


Figure 109 — Demand for initial contact (UML representation)

11.2.2 Referral

Term:	<i>referral</i>	
Definition: demand for care where a <i>healthcare professional</i> asks a <i>healthcare provider</i> to accept a <i>care period mandate</i>		
NOTE A <i>referral</i> transfer the continuity responsibility for the <i>health issues</i> specified in the <i>referral</i> .		
EXAMPLE	A <i>referral</i> from an orthopaedic surgeon to a rehabilitation service.	
Specialization of	Generalization of	
demand for care		
Association from	Association name	Association to
0..1 referral	initiates	0..1 initial contact
1 healthcare professional	issues	0..* referral

A model showing the associations of this concept is shown in Figure 110.

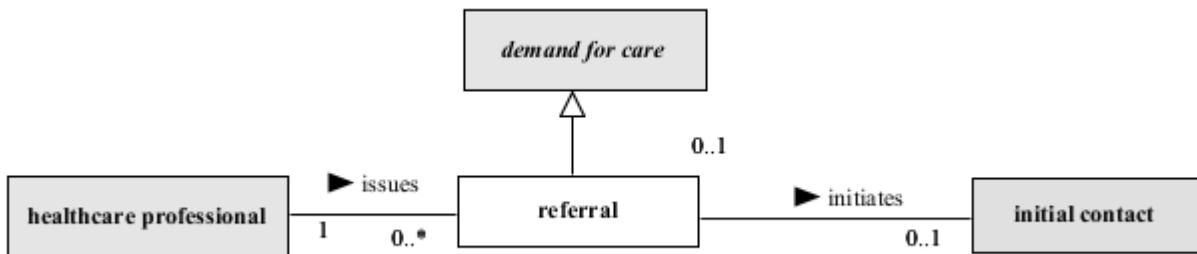


Figure 110 — Referral (UML representation)

11.2.3 Request

Term:	<i>request</i>	
Synonym:	order, healthcare provider activity request	
Definition: <i>demand for care where a healthcare professional asks a healthcare provider to perform one or more healthcare provider activities</i>		
NOTE 1 A request is put forward by a <i>healthcare professional</i> within a <i>healthcare process</i> .		
NOTE 2 The responsibility for the requested <i>healthcare provider activities</i> is held by the performer but they will be performed under the <i>care period mandate</i> of the requester.		
NOTE 3 A <i>healthcare provider</i> may accept or decline a <i>request</i> (order) to perform <i>healthcare activities</i> .		
EXAMPLE Request for an assessment, an operation, a wheelchair etc.		
Specialization of	Generalization of	
demand for care		
Association from	Association name	Association to
1 healthcare professional	issues	0..* request

A model showing the associations of this concept is shown in Figure 111.

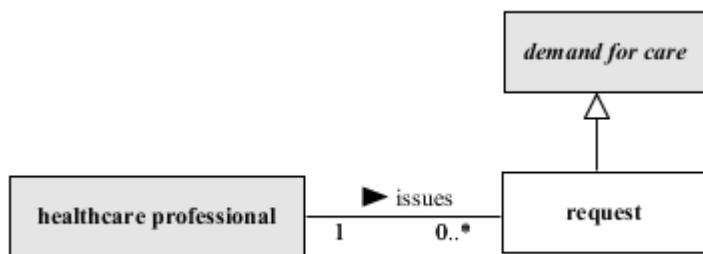


Figure 111 — Request (UML representation)

11.2.4 Reason for demand for care

Term:	<i>reason for demand for care</i>		
Definition:	<i>subject of care's or a subject of care proxy's perception of health needs motivating a demand for care</i>		
NOTE There are needs for both direct (investigating and treatment activities) and indirect (assessments, planning, evaluation etc.) <i>healthcare activities</i> .			
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

A model showing the associations of this concept is shown in Figure 112.

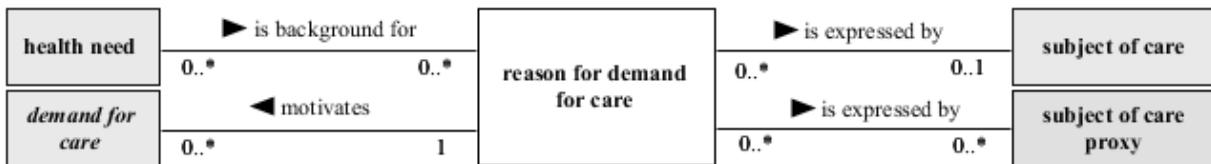


Figure 112 — Reason for demand for care (UML representation)

11.3 Healthcare mandate

Term: <i>healthcare mandate</i>
Synonym: health mandate, healthcare commission
Definition: commission based on a commitment and either an <i>informed consent</i> or an <i>authorization by law</i> , regulating the rights and obligations of one <i>healthcare actor</i> providing <i>healthcare activities</i> for a <i>subject of care</i>
NOTE 1 A <i>healthcare mandate</i> can be explicit or implicit
NOTE 2 Information about new <i>healthcare mandates</i> and changes that have occurred regarding existing <i>healthcare mandates</i> should be made available for concerned <i>healthcare actors</i> via recordings in <i>health records</i> .
NOTE 3 A <i>healthcare mandates</i> assigned by one <i>healthcare actor</i> and assigned to another <i>healthcare actor</i> .
NOTE 4 Relevant information related to <i>healthcare mandates</i> (e.g. <i>demands for care</i> , <i>informed consents</i> , <i>dissents</i> , <i>healthcare commitments</i> etc.), are recorded in <i>health records</i>
NOTE 5 In EN 13940-1:2007 health mandate was the preferred term for this concept.

Specialization of	Generalization of
	demand mandate
	care period mandate
	continuity facilitator mandate
	mandate to export personal data

Association from	Association name	Association to	
1..*	healthcare mandate	concerns	1 subject of care
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
1..*	healthcare provider activity	requires	1..* healthcare mandate
1..*	healthcare third party activity	requires	0..* healthcare mandate

A model showing the associations of this concept is shown in Figure 113.

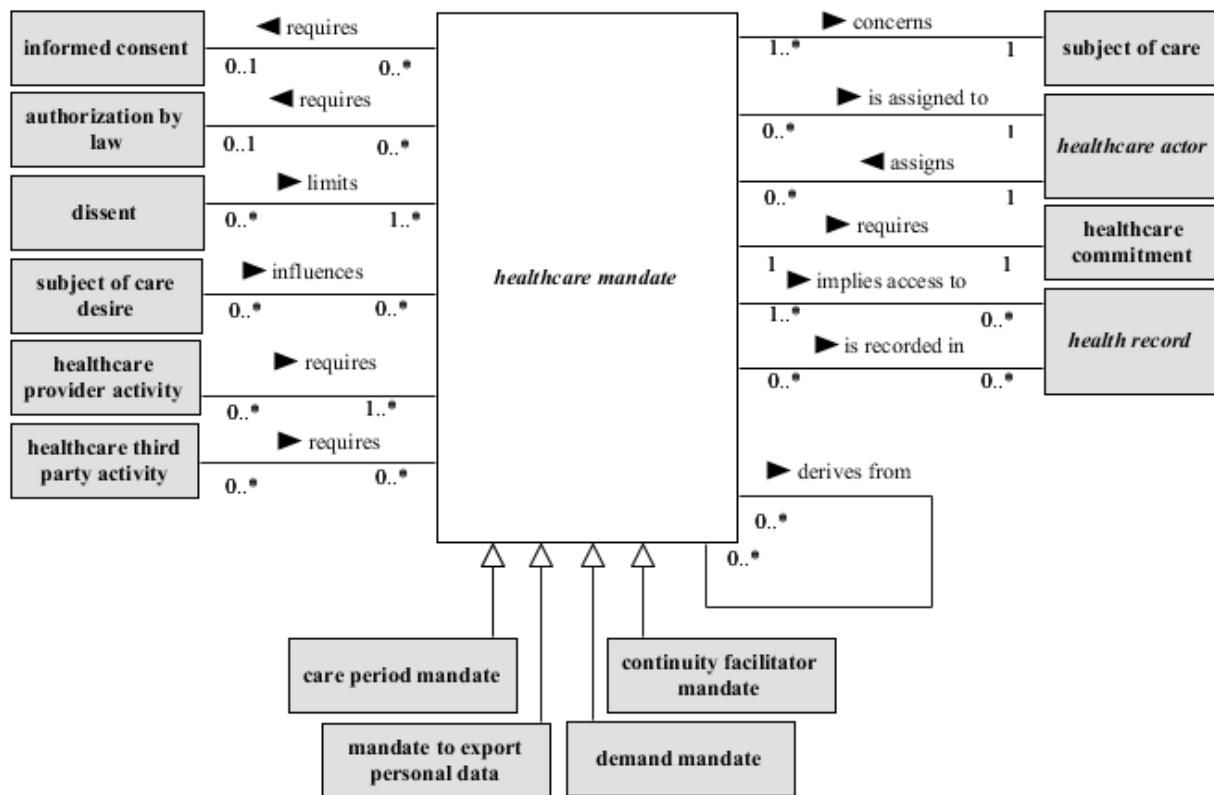


Figure 113 — Healthcare mandate (UML representation)

11.3.1 Demand mandate

Term: <i>demand mandate</i>		
Synonym: demand commission		
Definition: <i>healthcare mandate</i> implying the right and obligation to demand that <i>healthcare activities</i> are performed for the <i>subject of care</i>		
NOTE 1 A <i>demand for care</i> is usually expressed by a <i>subject of care</i> him/herself, but there are circumstances where the <i>subject of care</i> is not in the position of expressing a <i>demand for care</i> . In that case, it has to be expressed on their behalf by another person.		
NOTE 2 Within certain jurisdictions a generic <i>demand mandate</i> 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		
<ul style="list-style-type: none"> A <i>subject of care</i> requesting healthcare from a GP. Care for a child requested by a parent. In some jurisdictions, a passer-by is obliged by law to seek care for any endangered person, for example unconscious after a road accident. 		
Specialization of	Generalization of	
healthcare mandate		
Association from	Association name	Association to
1 demand for care	legitimizes	1 demand mandate
0..* demand mandate	has topic	1..* health issue
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 data

A model showing the associations of this concept is shown in Figure 114.

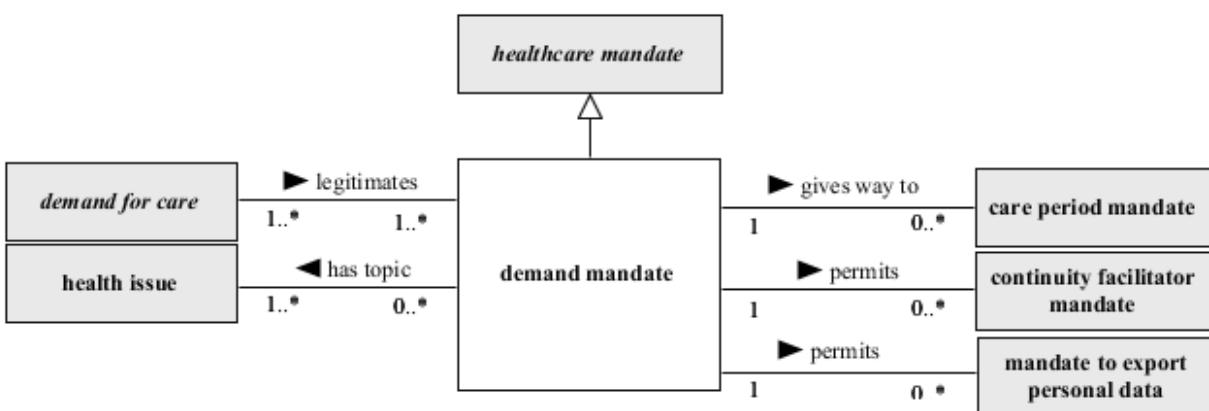


Figure 114 — Demand mandate (UML representation)

11.3.2 Care period mandate

Term:	<i>care period mandate</i>	
Synonyms:	healthcare period mandate, care mandate, care commission, clinical process commission, care process commission	
Definition: <i>healthcare mandate assigned to a healthcare provider to perform healthcare provider activities in a mandated period of care</i>		
NOTE 1 A <i>care period mandate</i> assigned to a <i>healthcare provider</i> provides the framework for a <i>mandated period of care</i> .		
NOTE 2 A <i>care period mandate</i> may be an agreement between the <i>subject of care</i> and a <i>healthcare provider</i> to perform specified <i>healthcare activities</i> .		
NOTE 3 In EN 13940-1:2007 care mandate was the preferred term for this concept.		
Specialization of	Generalization of	
healthcare mandate		
Association from	Association name	Association to
0..* care period mandate	has topic	1..* health issue
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 mandated period of care	has framework	1 care period mandate
1 healthcare provider	is able to be assigned	1..* care period mandate

A model showing the associations of this concept is shown in Figure 115.

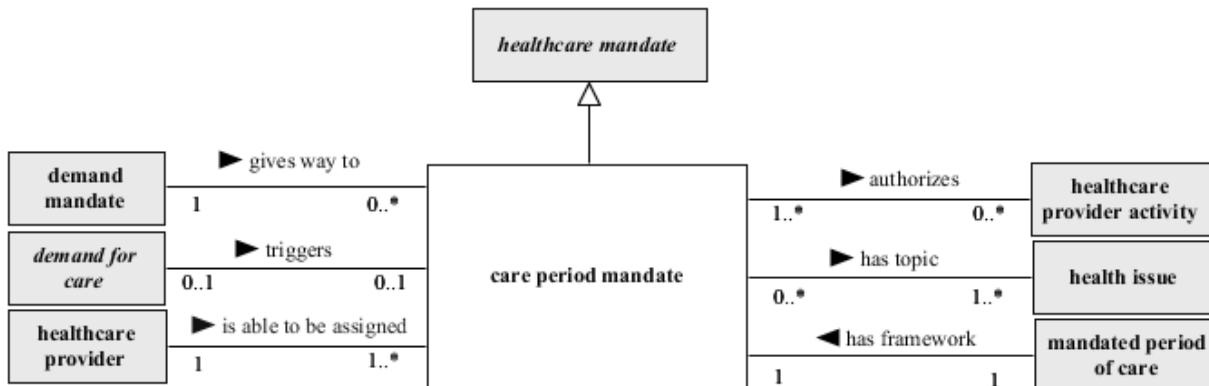


Figure 115 — Care period mandate (UML representation)

11.3.3 Continuity facilitator mandate

Term: <i>continuity facilitator mandate</i>		
Synonyms: continuity facilitator commission, continuity facilitator permission		
Definition: <i>healthcare mandate</i> assigning the right and obligation to ensure that the sequence and timeliness of the <i>healthcare activities</i> in a <i>healthcare process</i> are monitored and coordinated		
NOTE 1 Beyond solely assuming the function described above, a continuity facilitator may also assume the function of a lead and/or coordinator of <i>healthcare activities</i> delivered to the <i>subject of care</i>		
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		
EXAMPLE A mandate assigned to a coordinating nurse, to a lead GP etc.		
Specialization of	Generalization of	
healthcare mandate		
Association from	Association name	Association to
0..* continuity facilitator mandate	has topic	0..* health issue thread
1 demand mandate	permits	0..* continuity facilitator mandate
0..* continuity facilitator mandate	assigns the right and obligation to monitor and coordinate	1 healthcare process

A model showing the associations of this concept is shown in Figure 116.

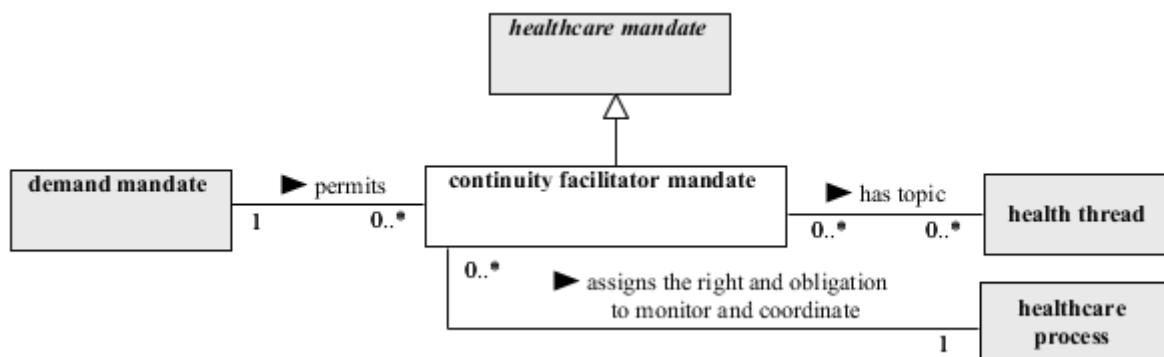


Figure 116 — Continuity facilitator mandate (UML representation)

11.3.4 Mandate to export personal data

Term: <i>mandate to export personal data</i>			
Synonym: permission to export personal data			
Definition: <i>healthcare mandate implying the right to communicate health record extracts</i>			
EXAMPLES			
<ul style="list-style-type: none"> • A request to a doctor to write a letter to a medical specialist stating the reasons of a referral • A request to a GP by a <i>subject of care</i> for the transfer of his or her <i>health record</i> to another GP, when that <i>subject of care</i> moves to another part of the country. 			
Specialization of	Generalization of		
healthcare mandate			
Association from	Association name	Association to	
0..* mandate to export personal data	has topic	1..*	healthcare matter
1..* mandate to export personal data	implies the right to communicate	1..*	health record extracts
1 healthcare professional	has assigned	0..*	mandate to export personal data
1 demand mandate	permits	0..*	mandate to export personal data
1..* health record extract	is entitled by	1	mandate to export personal data

A model showing the associations of this concept is shown in Figure 117.

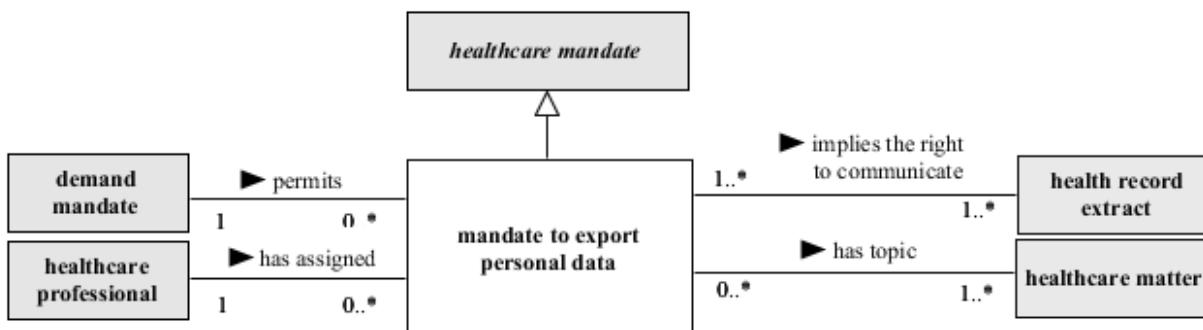


Figure 117 — Mandate to export personal data (UML representation)

11.3.5 Subject of care desire

Term: <i>subject of care desire</i>			
Definition: desire expressed by the <i>subject of care</i> or the <i>subject of care proxy</i> regarding the performance of certain <i>healthcare activities</i>			
EXAMPLES No blood transfusion, cultural or religious preference, do not resuscitate, allow natural death			
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

A model showing the associations of this concept is shown in Figure 118.

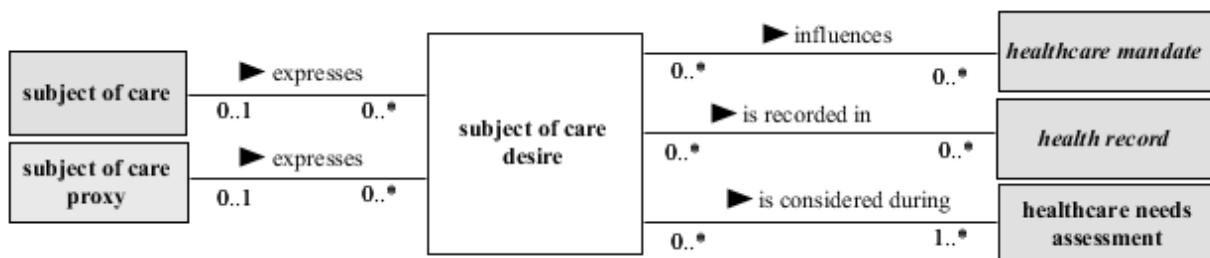


Figure 118 — Subject of care desire (UML representation)

11.4 Informed consent

Term: <i>informed consent</i>				
Definition: permission to perform <i>healthcare activities</i> , voluntarily given by a <i>subject of care</i> having <i>consent competence</i> , or by a <i>subject of care proxy</i> , after having been informed about the purpose and the possible results of the <i>healthcare activities</i>				
NOTE A <i>healthcare mandate</i> requires either <i>informed consent</i> or <i>authorization by law</i> .				
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

A model showing the associations of this concept is shown in Figure 119.

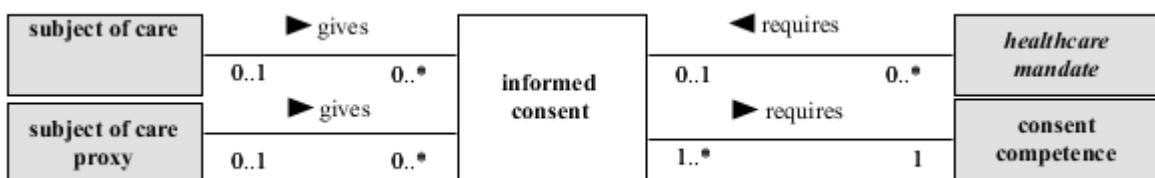


Figure 119 — Informed consent (UML representation)

11.4.1 Dissent

Term: <i>dissent</i>			
Definition: refusal to permit specific <i>healthcare activities</i> to be performed			
Association from	Association name	Association to	
1..* 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

A model showing the associations of this concept is shown in Figure 120.

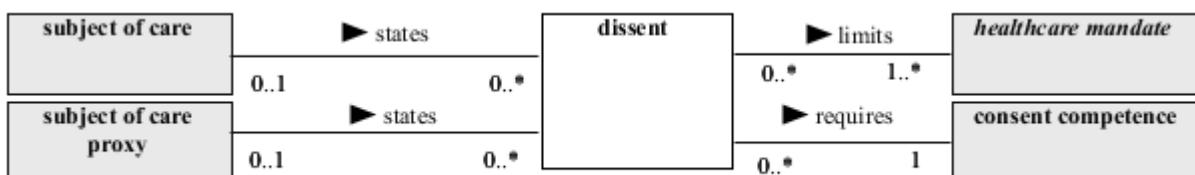


Figure 120 — Dissent (UML representation)

11.5 Consent competence

Term: <i>consent competence</i>			
Definition: the capability of the <i>subject of care</i> and/or the <i>subject of care proxy</i> to give <i>informed consent</i> or <i>dissent</i>			
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
1 subject of care	has	0..1	consent competence

A model showing the associations of this concept is shown in Figure 121.

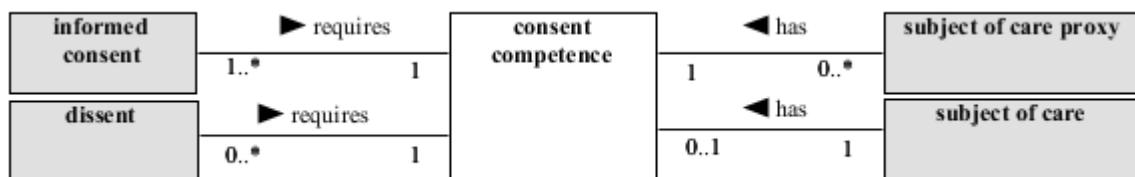


Figure 121 — Consent competence (UML representation)

11.6 Authorization by law

Term:	<i>authorization by law</i>	
Definition:	provision in legislation that in certain circumstances may overrule the need for <i>informed consent</i>	
NOTE A <i>healthcare mandate</i> requires either <i>informed consent</i> or <i>authorization by law</i> .		
Association from	Association name	Association to
0..* healthcare mandate	requires	0..1 authorization by law

A model showing the associations of this concept is shown in Figure 122.

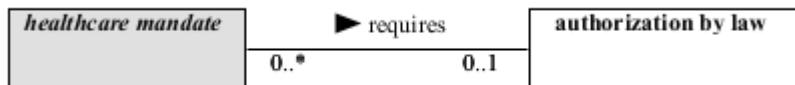


Figure 122 — Authorization by law (UML representation)

11.7 Healthcare commitment

Term:	<i>healthcare commitment</i>
Synonym:	care commitment
Definition: acceptance of a <i>healthcare mandate</i> by the <i>healthcare actor</i> to whom it is assigned	
<p>NOTE 1 The <i>healthcare commitment</i> is the promise by the <i>healthcare actor</i> to perform <i>healthcare activities</i>. This also means that the <i>healthcare provider</i> accepts and confirms the pending <i>healthcare mandate</i> issued through the proposed care plan.</p> <p>It is only once the <i>healthcare commitment</i> has been stated that an effective <i>healthcare mandate</i> exists and will be the legal framework for all <i>healthcare activities</i> of the subsequent <i>healthcare process</i>.</p> <p>NOTE 2 Implicitly, a <i>healthcare commitment</i> results from a dialogue with the <i>subject of care</i> or someone on behalf of the <i>subject of care</i> within a <i>healthcare needs assessment</i></p>	

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
1 healthcare provider	states	1..* healthcare commitment

A model showing the associations of this concept is shown in Figure 123.

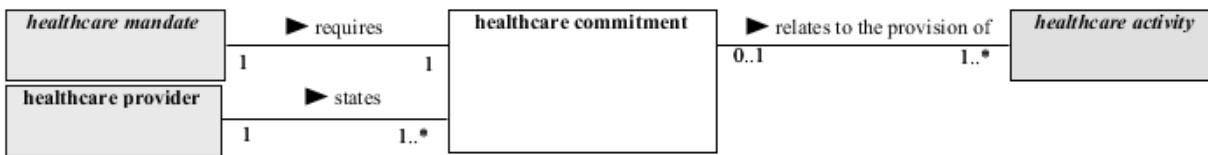


Figure 123 — Healthcare commitment (UML representation)

12. Health information (data) management in continuity of care

12.1 General

A model showing the associations between the concepts related to health information (data) management in continuity of care and the other concepts defined in this International Standard is shown in Figure 124.

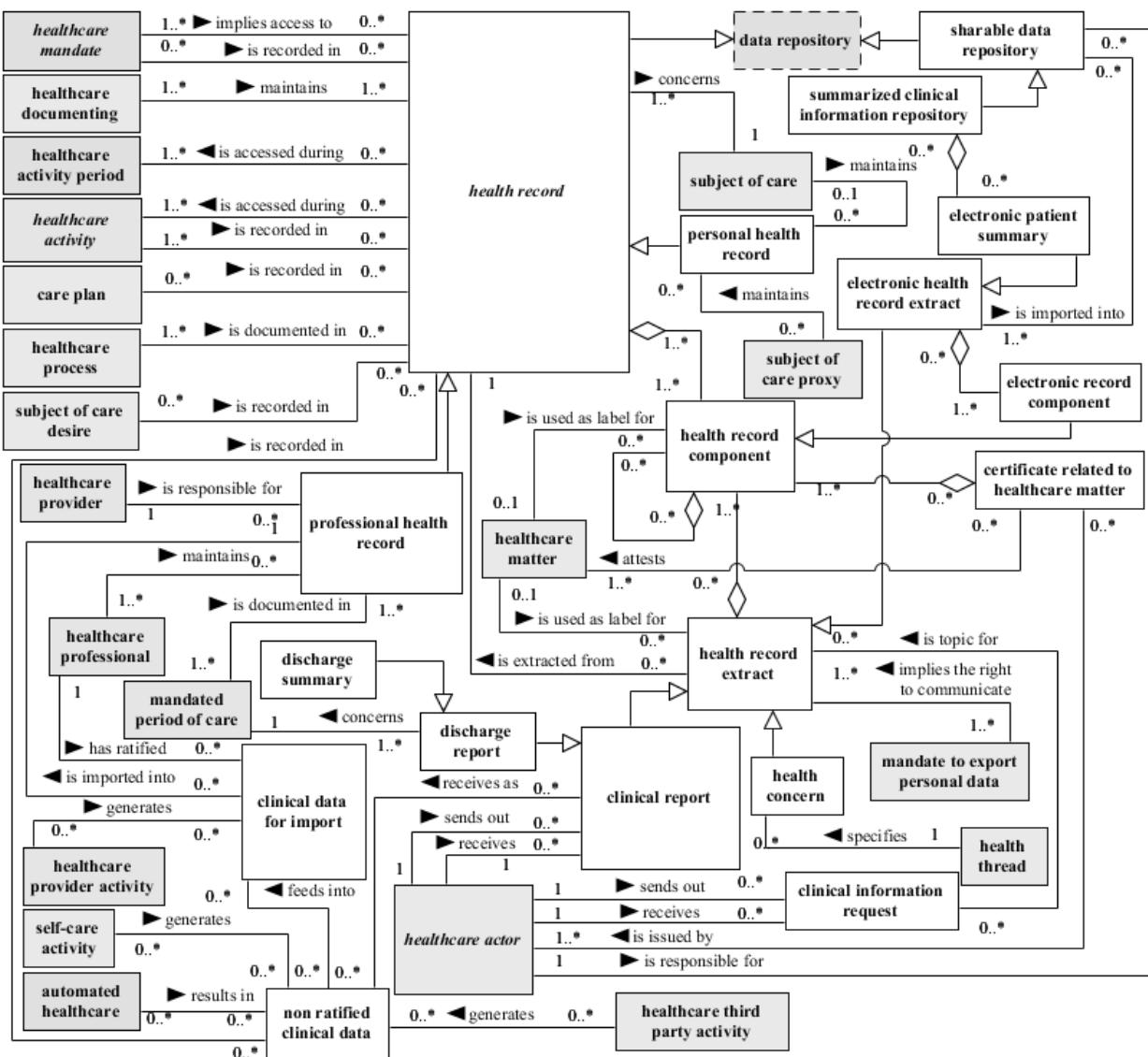


Figure 124 — Comprehensive UML diagram of health data management in continuity of care

12.2 Health record

Term:	<i>health record</i>					
Definition: <i>data repository</i> regarding the health and care of a <i>subject of care</i>						
NOTE 1 The term electronic health record may be used for a <i>health record</i> where all information is stored on electronic media. However, this concept is not formally defined in this International Standard.						
NOTE 2 A <i>health record</i> may include, for example, medical records, dental records, social care records.						
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			
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 clinical data	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			

A model showing the associations of this concept is shown in Figure 125.

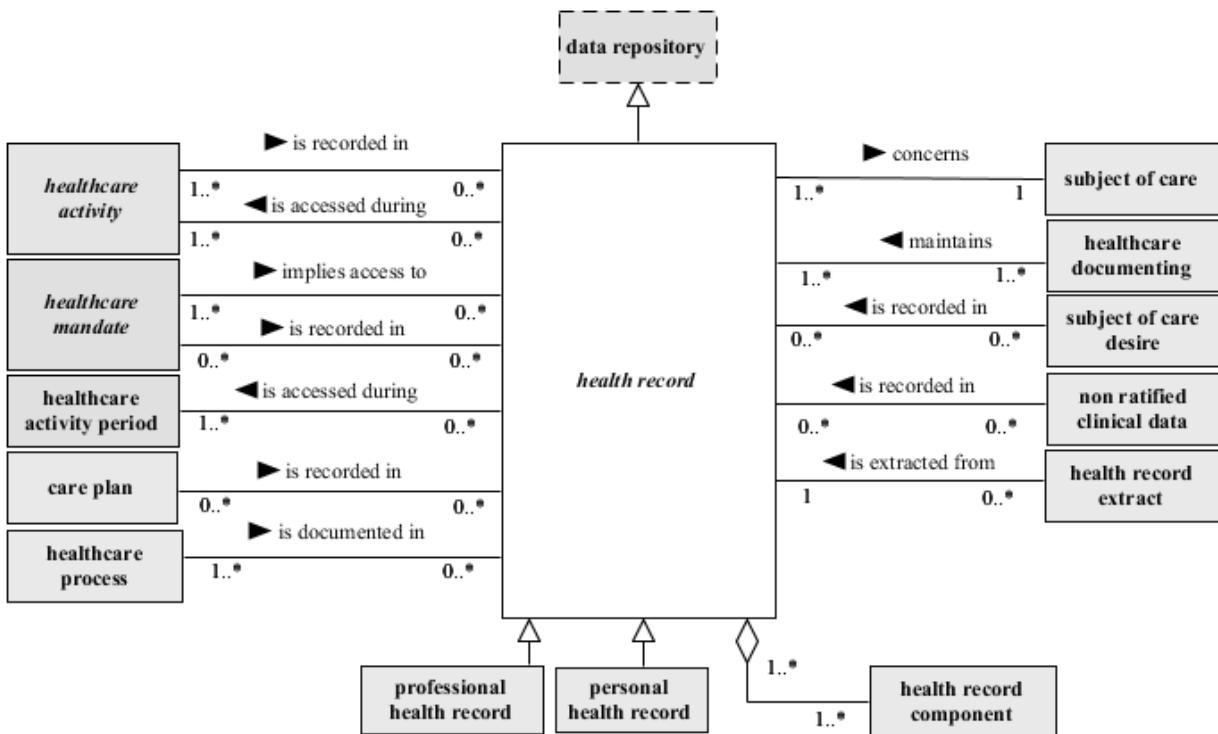


Figure 125 — Health record (UML representation)

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		
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.		
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..* clinical data for import	is imported into	1 professional health record

A model showing the associations of this concept is shown in Figure 126.

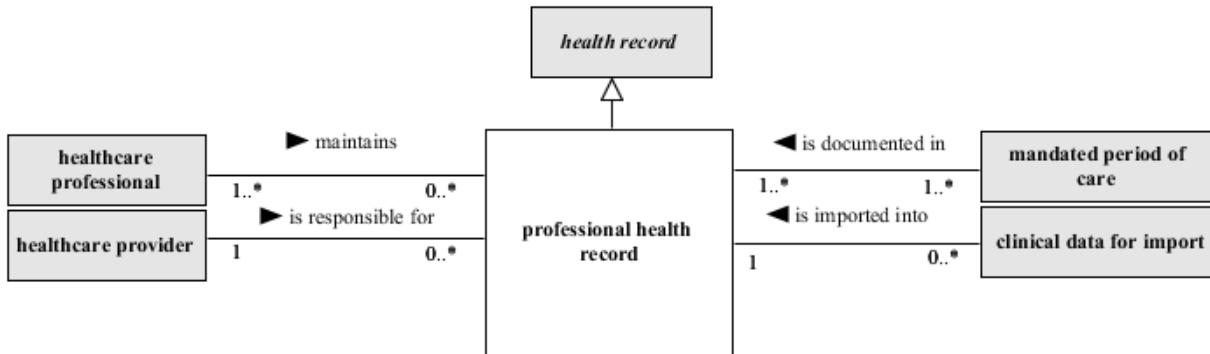


Figure 126 — Professional health record (UML representation)

12.2.2 Personal health record

Term:	<i>personal health record</i>			
Abbreviation:	PHR			
Definition: <i>health record held and maintained by the subject of care or a subject of care proxy</i>				
NOTE A subject of care may allow any healthcare actor to access and/or contribute to the 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		

A model showing the associations of this concept is shown in Figure 1227.

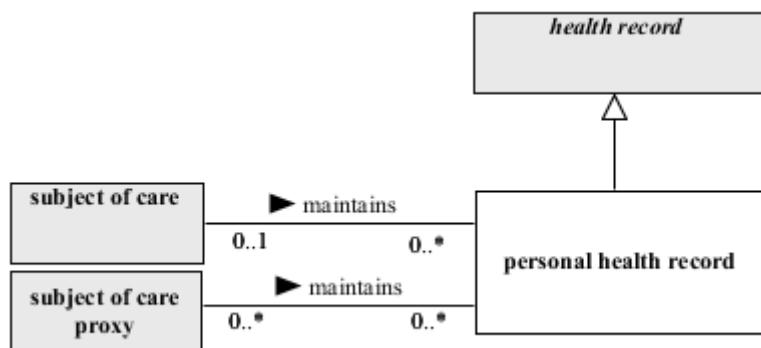


Figure 127 — Personal health record (UML representation)

12.3 Sharable data repository

Term:	<i>sharable data repository</i>	
Definition: <i>data repository containing exclusively electronic health record extracts, accessible for duly authorised healthcare actors independent of their organizational affiliation and placed under the custody of a healthcare actor</i>		
NOTE 1 A <i>sharable data repository</i> has to be placed under the custody of a <i>healthcare actor</i> in order to assure and maintain its consistency.		
NOTE 2 In EN 13940-1:2007 <i>sharable data repository</i> was defined as ' <i>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</i> '.		
Specialization of	Generalization of	
data repository	summarized clinical 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 exported from	0..* sharable data repository

A model showing the associations of this concept is shown in Figure 128.

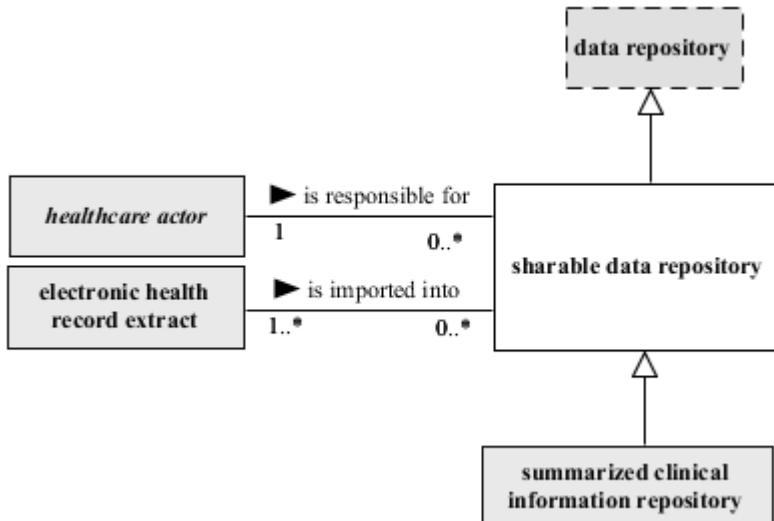


Figure 128 — Sharable data repository (UML representation)

12.3.1 Summarized clinical information repository

Term:	<i>summarized clinical information repository</i>
Synonym:	patient summary repository
Definition: <i>data repository containing summarized information for healthcare coordination and the continuity of care</i>	
Specialization of	Generalization of
data repository	
Component of	Aggregation of
	0..* electronic patient summary

A model showing the associations of this concept is shown in Figure 129.

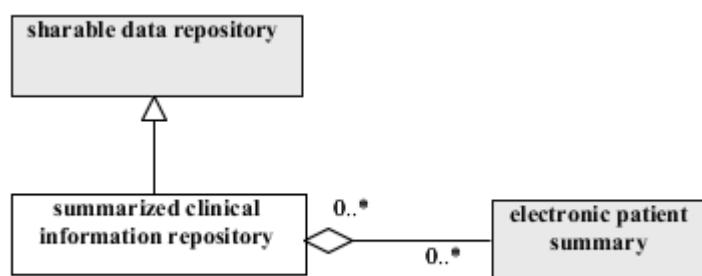


Figure 129 — Summarized clinical information repository (UML representation)

12.4 Health record component

Term:	<i>health record component</i>			
Definition: part of a <i>health record</i> that is identifiable for the purposes of referencing and revision				
NOTE 1 This International Standard defines one <i>health record component</i> specialization, the <i>electronic record component</i> . However, as the content of a <i>health record</i> is not limited to information in electronic format, the content of <i>health record components</i> may be in formats other than electronic.				
NOTE 2 A <i>health record component</i> may itself result from an aggregation of multiple <i>health record components</i> .				
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 issue	is used as label for	0..* health record component		

A model showing the associations of this concept is shown in Figure 130.

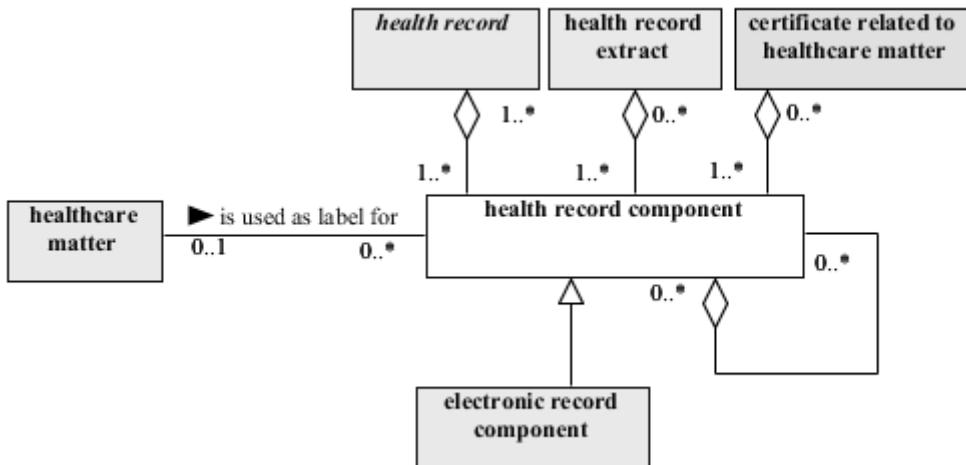


Figure 130 — Health record component (UML representation)

12.5 Electronic record component

Term:	<i>electronic record component</i>
Synonym:	record component
Definition:	<i>health record component</i> which only includes information in electronic format
NOTE	In EN 13940-1:2007 record component was the preferred term for this concept.
Specialization of	Generalization of
health record component	
Component of	Aggregation of
0..* electronic health record extract	

A model showing the associations of this concept is shown in Figure 131.

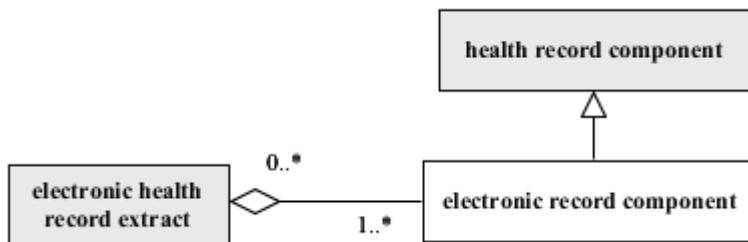


Figure 131 — Electronic record component (UML representation)

12.6 Clinical information request

Term:	<i>clinical information request</i>	
Synonym:	specific clinical information request	
Definition: request sent out by a <i>healthcare actor</i> to another <i>healthcare actor</i> for specific <i>clinical information</i> needed for the provision of healthcare to a <i>subject of care</i>		
NOTE 1 In order to fulfil the request, a <i>mandate to export personal data</i> is needed.		
NOTE 2 In EN 13940-1:2007 specific clinical information request was the preferred term for this concept.		
Association from	Association name	Association to
0..* clinical information request	is topic for	0..* health record extract
1 healthcare actor	sends out	0..* clinical information request
1 healthcare actor	receives	0..* clinical information request

A model showing the associations of this concept is shown in Figure 132.

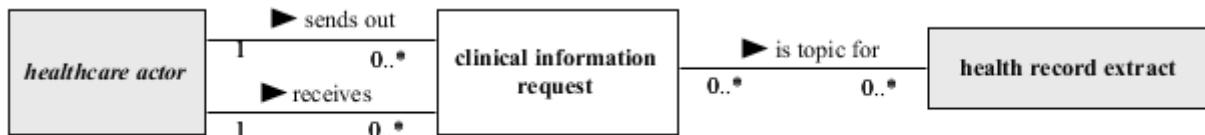


Figure 132 — Clinical information request (UML representation)

12.7 Health record extract

Term: <i>health record extract</i>		
Definition: part or a <i>health record</i> grouped for the purpose of communication NOTE extract => copy		
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 data	implies the right to communicate	1..* health record extract
0..1 healthcare matter	is used as label for	0..* health record extract
0..* clinical information request	is topic for	0..* health record extract

A model showing the associations of this concept is shown in Figure 133.

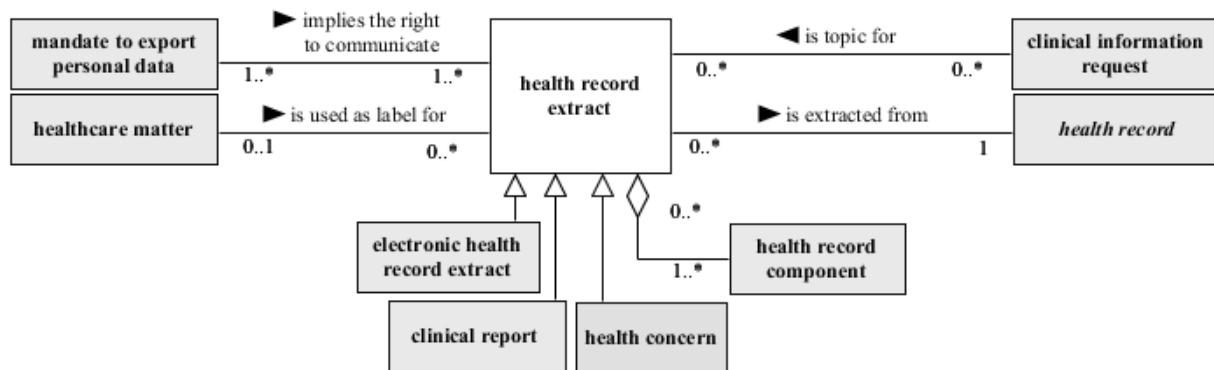


Figure 133 — Health record extract (UML representation)

12.8 Electronic health record extract

Term:	<i>electronic health record extract</i>	
Synonym:	EHR extract	
Abbreviation:	EHR extract	
Definition: <i>health record extract consisting solely of electronic record components</i>		
NOTE 1	Provisions for the communication of <i>electronic health record extracts</i> are to be found in EN ISO 13606.	
NOTE 2	In EN 13940-1:2007 EHR extract was the preferred term for this concept.	
Specialization of	Generalization of	
health record extract	electronic patient summary	
Component of	Aggregation of	
	1..* electronic record component	
Association from	Association name	Association to
1..* health record extract	is imported into	0..* sharable data repository
0..* electronic health record extract	is exported from	0..* sharable data repository

A model showing the associations of this concept is shown in Figure 134.

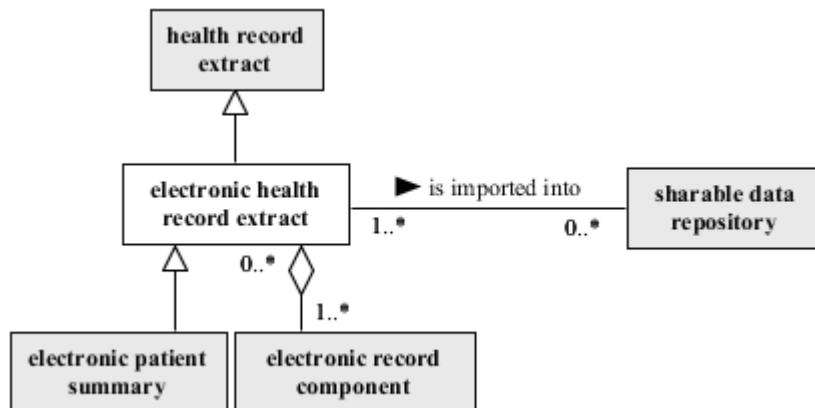


Figure 134 — Electronic health record extract (UML representation)

12.8.1 Electronic patient summary

Term:	<i>electronic patient summary</i>
Definition: <i>electronic health record extract containing essential clinical information intended for use by healthcare actors when performing both planned and unplanned healthcare activities</i>	
NOTE An <i>electronic patient summary</i> provides a <i>healthcare professional</i> with essential information needed for coordinated healthcare.	
Specialization of	Generalization of
electronic health record extract	
Component of	Aggregation of
0..* summarized clinical information repository	

A model showing the associations of this concept is shown in Figure 135.

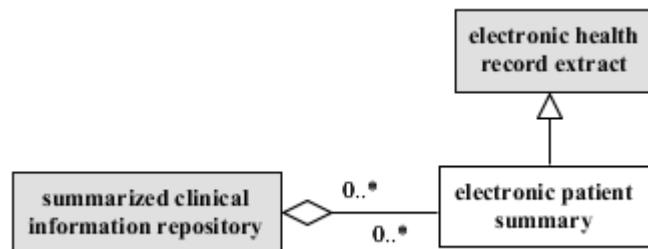


Figure 135 — Electronic patient summary (UML representation)

12.8.2 Clinical Report

Term:	<i>clinical report</i>	
Definition: <i>health record extract</i> conveying specifically focused clinical information in order to fulfil current information needs of the recipient		
EXAMPLES lab report, X-Ray report		
Specialization of	Generalization of	
health record extract	discharge report	
Association from	Association name	Association to
0..* clinical report	receives as	0..* non ratified clinical data
1 healthcare actor	sends out	0..* clinical report
1 healthcare actor	receives	0..* clinical report

A model showing the associations of this concept is shown in Figure 136.

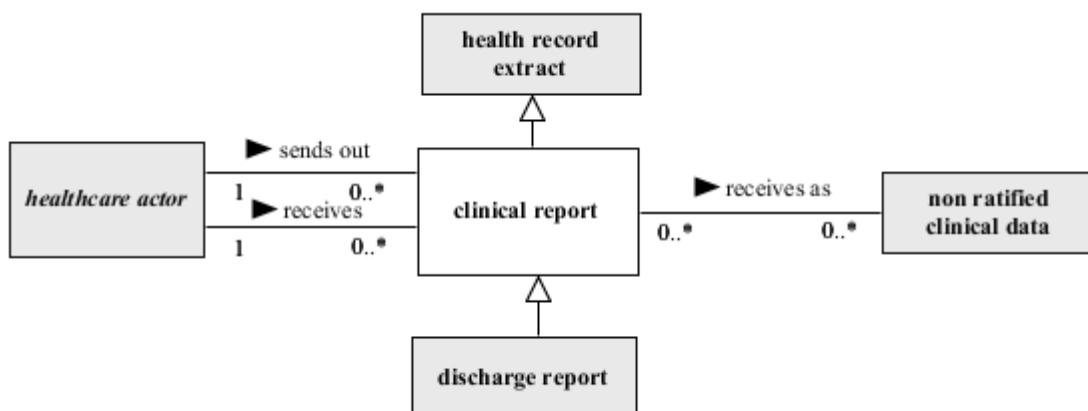


Figure 136 — Clinical report (UML representation)

12.8.2.1. Discharge report

Term:	<i>discharge report</i>	
Definition:	<i>clinical report concerning a completed, mandated period of care</i>	
EXAMPLE	Discharge letter	
Specialization of		Generalization of
clinical report		discharge summary
Association from	Association name	Association to
1..* discharge report	concerns	1 mandated period of care

A model showing the associations of this concept is shown in Figure 137.

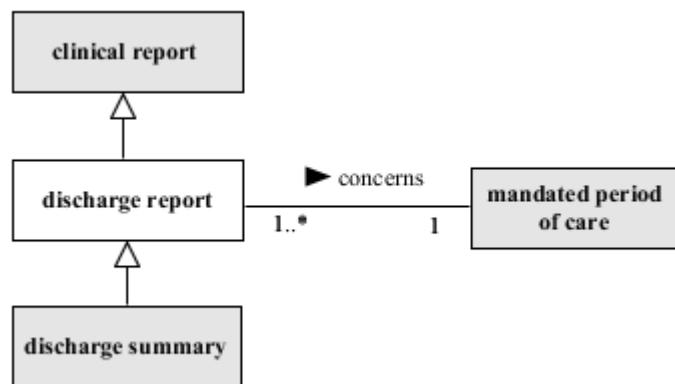


Figure 137 — Discharge report (UML representation)

12.8.1.2.1 Discharge summary

Term:	<i>discharge summary</i>
Definition: <i>discharge report summarizing a mandated period of care</i>	
<p>NOTE <i>Discharge summaries</i> are often meant to be processed so as to group hospital stays according to a statistically designed classification (such as the Diagnosis-Related Groups (DRGs) or other systems), usually for funding purposes.</p> <p>NOTE 2 One <i>mandated period of care</i> may be immediately followed by another; the next mandated healthcare provider will then be a main recipient of the <i>discharge summary</i>.</p> <p>NOTE 3 A <i>discharge summary</i> may be provided to the <i>subject of care</i>.</p>	
EXAMPLES	
<ul style="list-style-type: none"> • '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. 	
Specialization of	Generalization of
discharge report	

A model showing the associations of this concept is shown in Figure 138.

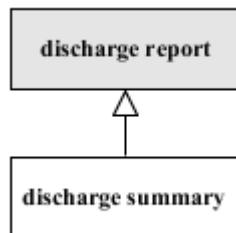


Figure 138 — Discharge summary (UML representation)

12.8.3 Health concern

Term:	<i>health concern</i>	
Definition: <i>health record extract</i> that includes all health record components associated with a <i>health thread</i> for a specific concern		
NOTE 1 A concern is gathered information to support continuity of care for a subject of care. A health thread includes 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).		
Specialization of	Generalization of	
health record extract		
Association from	Association name	Association to
1 health thread	specifies	0..* health concern

A model showing the associations of this concept is shown in Figure 139.

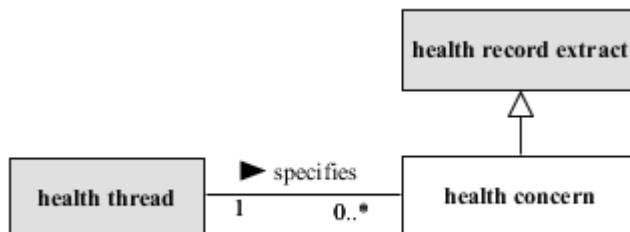


Figure 139 — Health concern (UML representation)

12.8.4 Certificate related to a healthcare matter

Term:	<i>certificate related to a healthcare matter</i>		
Definition:	official document issued by a <i>healthcare actor</i> attesting <i>healthcare matters</i> relating to a <i>subject of care</i>		
EXAMPLES	Birth certificate, death certificate, health certificate, health insurance certificate		
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

A model showing the associations of this concept is shown in Figure 140.

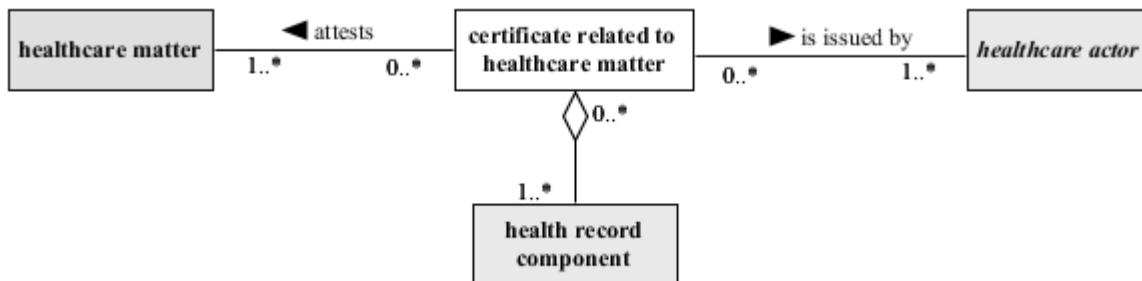


Figure 140 — Certificate related to a healthcare matter (UML representation)

12.9 Non ratified clinical data

Term:	<i>non ratified clinical data</i>	
Definition: <i>clinical data</i> the relevance of which has not been assessed and explicitly stated as valid by a <i>healthcare professional</i>		
<p>NOTE 1 <i>Data</i> that has been received and is proposed for incorporation in a <i>professional health record</i> may not yet have been reviewed for validity or context by the <i>healthcare professional</i>, and as such its' accuracy may remain arguable. In this respect, clinical ratification differs both from attesting data for the needs of an audit trail, or from committing data in the perspective of sending out messages containing clinical data, outlined in EN 13606-1:2007.</p> <p>NOTE 2 Regardless of the technical process meant practically, <i>clinical data</i> cannot be 'inserted' into a <i>professional health record</i> unless ratified by a <i>healthcare professional</i>. 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 <i>healthcare professional</i> would directly import <i>clinical data</i> from a <i>sharable data repository</i> into the local <i>health record</i> they hold. In the case where this import resulted from a request to the <i>healthcare actor</i> in the custody of whom the <i>sharable data repository</i> is placed, that <i>clinical data</i> would then need validation.</p>		
Specialization of	Generalization of	
clinical data		
Association from	Association name	Association to
0..* non ratified clinical data	is recorded in	0..* health record
0..* non ratified clinical data	changes state to	0..* clinical data for import
0..* clinical report	receives as	0..* non ratified clinical data
0..* self-care activity	generates	0..* non ratified clinical data
0..* healthcare third party activity	generates	0..* non ratified clinical data
0..* automated healthcare	results in	0..* non ratified clinical data

A model showing the associations of this concept is shown in Figure 141.

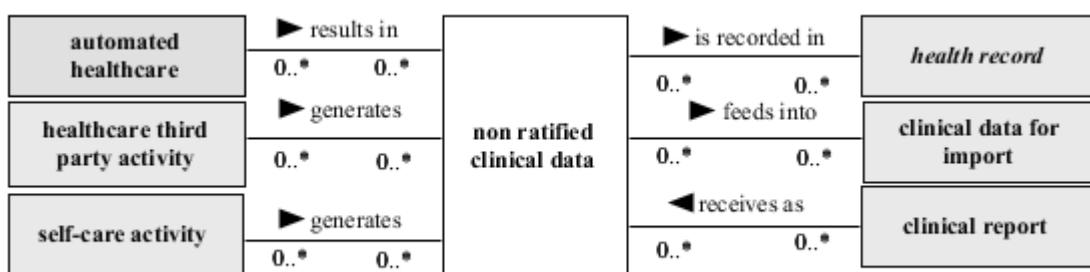


Figure 141 — Non-ratified clinical data (UML representation)

12.10 Clinical data for import

Term:	<i>clinical data for import</i>		
Definition:	<i>clinical data</i> that is a candidate for import into a <i>professional health record</i> after a <i>healthcare professional</i> has confirmed its clinical relevance to that professional health record		
Specialization of	Generalization of		
clinical data			
Association from	Association name	Association to	
0..* clinical data for import	is imported into	1	professional health record
0..* non ratified clinical data	changes state to	0..*	clinical data for import
1 healthcare professional	has ratified	0..*	clinical data for import
0..* healthcare provider activity	generates	0..*	clinical data for import

A model showing the associations of this concept is shown in Figure 142.

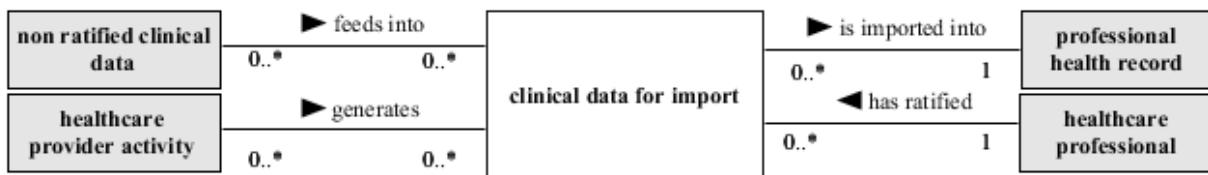


Figure 142 — Clinical data for import (UML representation)

13. Conformance

13.1 Where a concept defined in this standard is used it shall be labelled by the preferred term or a synonym, acronym or abbreviation defined in this standard

13.2 Where a term labelling a concept defined in this 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 standard are used all the relationships between these specializations, as defined in the normative provisions of this International Standard, including their relationship type, shall be used. Multiplicities shall be within the limits specified in this standard.

NOTE Conformant products will include other standards, concept models, class models, other models, information systems etc.

Annex A

14. Framework for the normative concepts in this standard (Informative)

14.1 Introduction

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 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.

Chapter 14.2 in this annex gives an overview of a general process approach applied in the development of this standard.

Chapter 14.3 gives an overview of the types of processes in healthcare organisations.

Chapter 14.4 presents a healthcare/clinical process model compatible with this standard.

An analysis of the relations between the basic clinical concepts of this standard and the model of the healthcare/clinical process is given in chapter 14.5; this clarifies traceability of the clinically oriented concepts to the clinical context.

Chapter 14.6 gives further traceability for non-clinical concepts in the broader context of health and care. This chapter gives traceability of all clauses of concepts to an information area model that includes clinical context with the supporting and managing areas around it.

14.2 Processes in general

The generic definition of a process, outlined in ISO 9000:2005, is a "set of interrelated or interacting activities which transforms inputs into outputs".

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 process
- the secondary resource inputs that are utilised 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 a product. The product may be a service if the results are not tangible. The products/services provided are received by the main customers of that organisation.

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 2 shows the general schematic representation of a process, with inputs, nested activities/processes, management, resource supply and outputs.

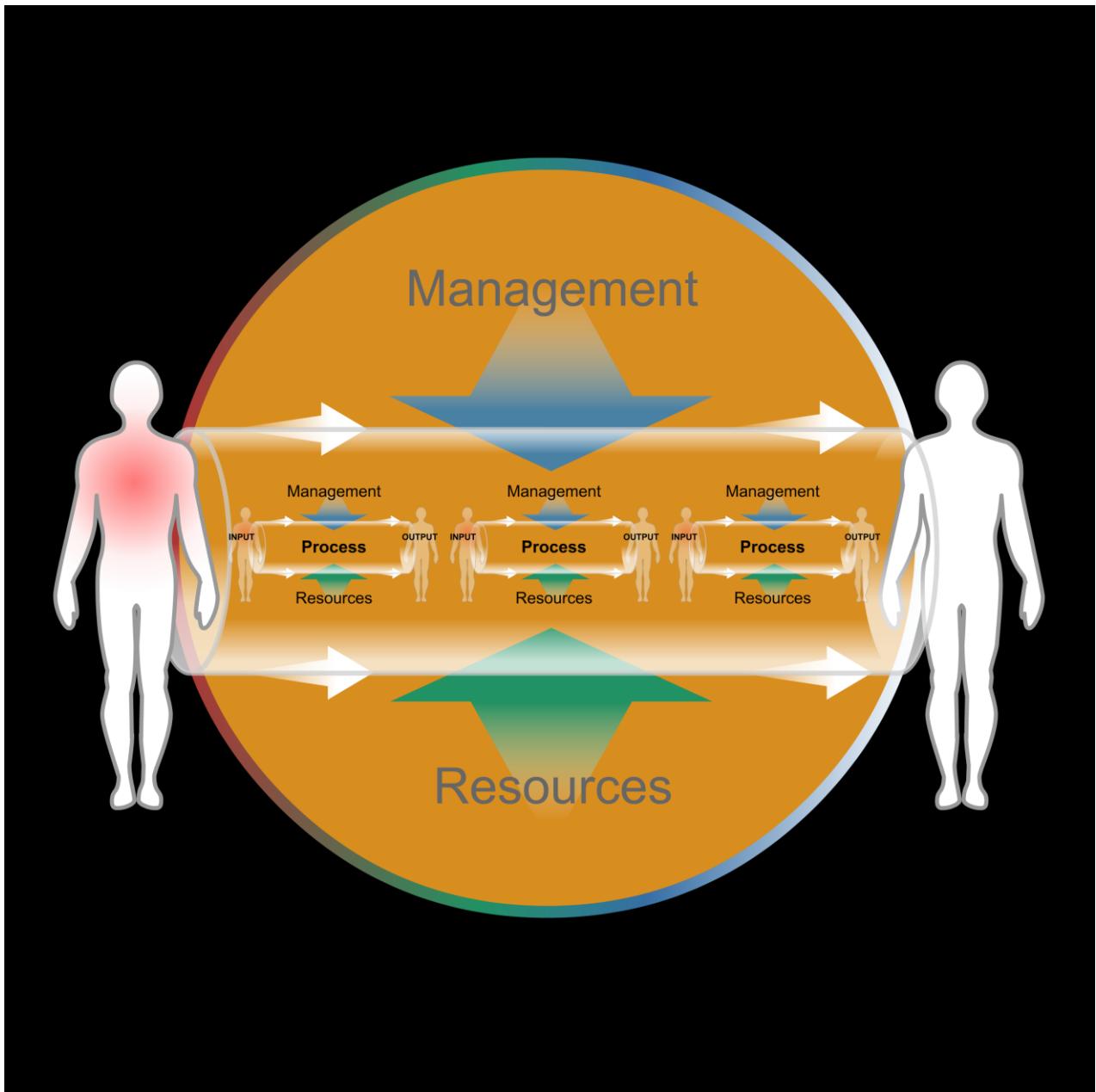


Figure 143 — Schematic general process (Informative)

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.

14.3 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.

14.4 Types of processes and workflow in healthcare

In this 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 can be identified:

- Healthcare- and clinical processes
- Healthcare research processes
- Healthcare educational processes

14.4.1 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 "products" in healthcare are healthcare services (the 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 as related to specified health issues. 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 needs 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 'clinical process concern' in this standard.

Like all kinds of processes the healthcare- and clinical processes are dependent upon management and resource support; as shown in Figure 144.

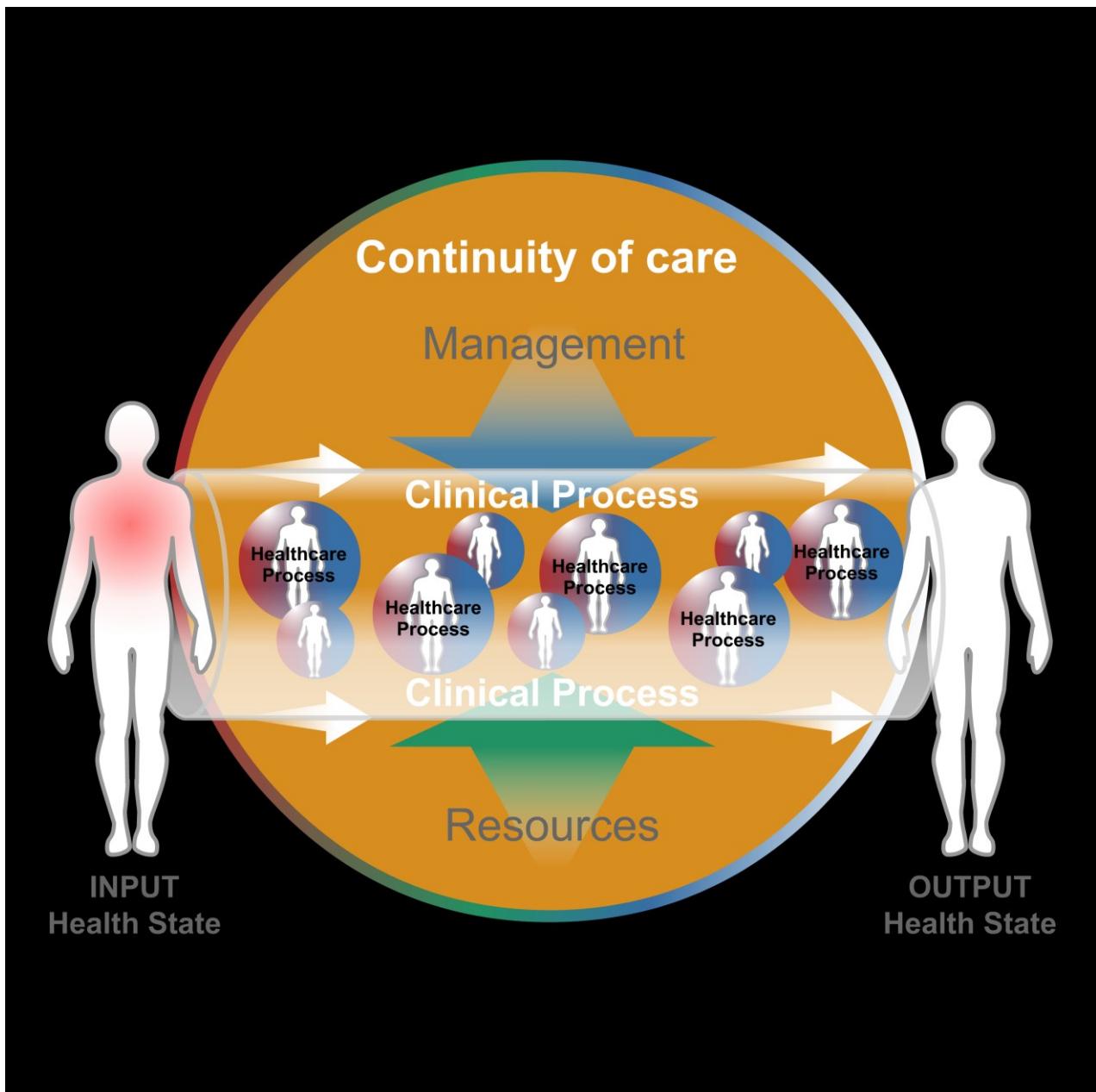


Figure 144 — The clinical process in continuity of care (Informative)

14.4.2 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 standard.

14.4.3 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 standard.

14.4.4 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*.

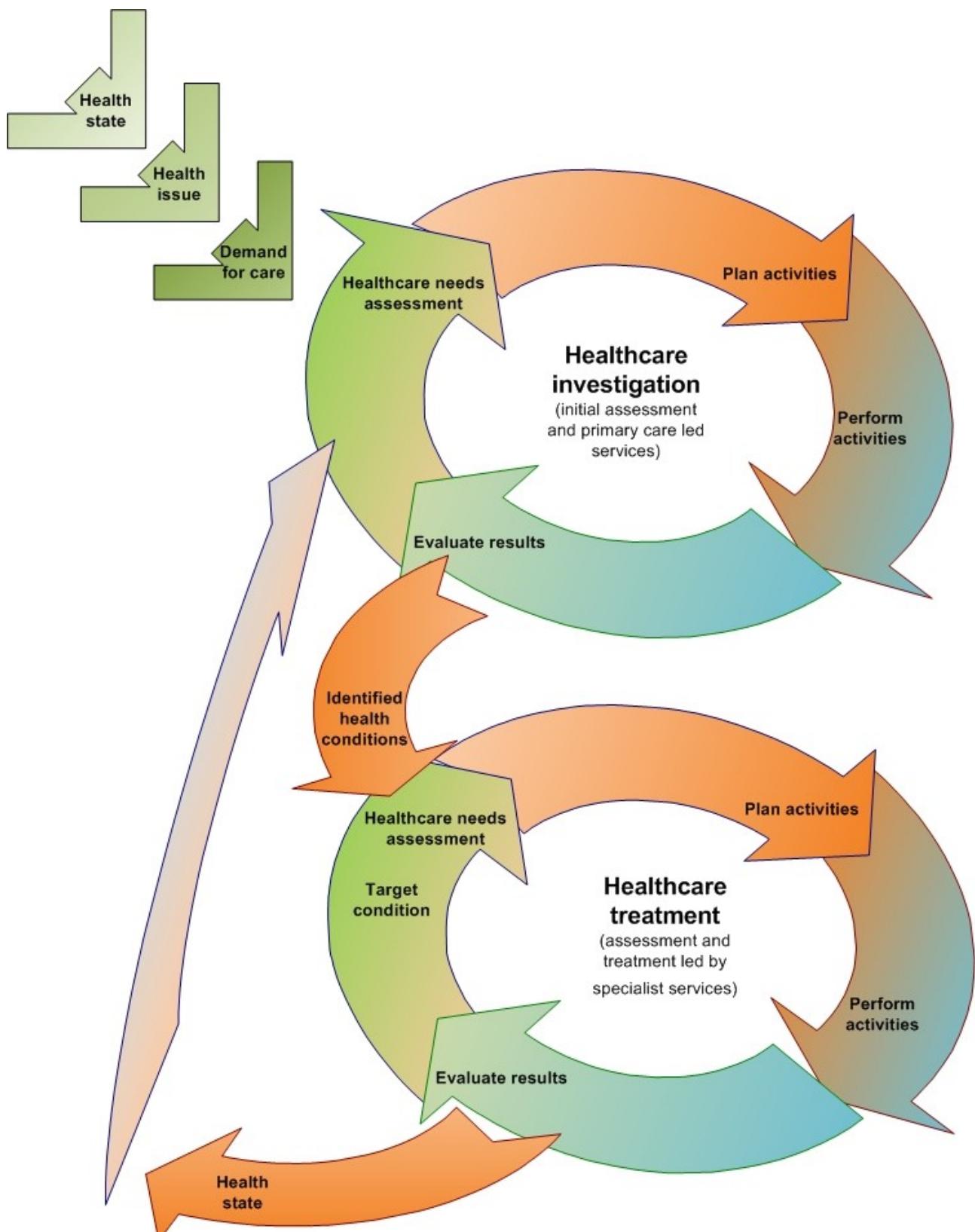
Workflow is not defined within this standard.

14.5 The Healthcare / Clinical process model

In the development of this 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 standard is shown in Figure 145

**Figure 145 – Main concepts of a clinical process (Informative)**

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 can be limited to the aspects found relevant within each system.

14.6 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 standard applies a modelling technique to achieve traceability, show the contextual interrelations, their comprehensiveness and provide a common understanding of the included concepts. This chapter of the annex includes a description and analysis of the healthcare/clinical process model presented in chapter 14.5. 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 chapter 14.7.

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 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 standard has a primary focus upon the *clinical process* on the assumption that this is an effective approach to support continuity of care.

The model 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*) and
- the additional concepts needed for the performance (management or resource support).

The figure 146 below show a schematic version of the healthcare/clinical process model from chapter 14.5.

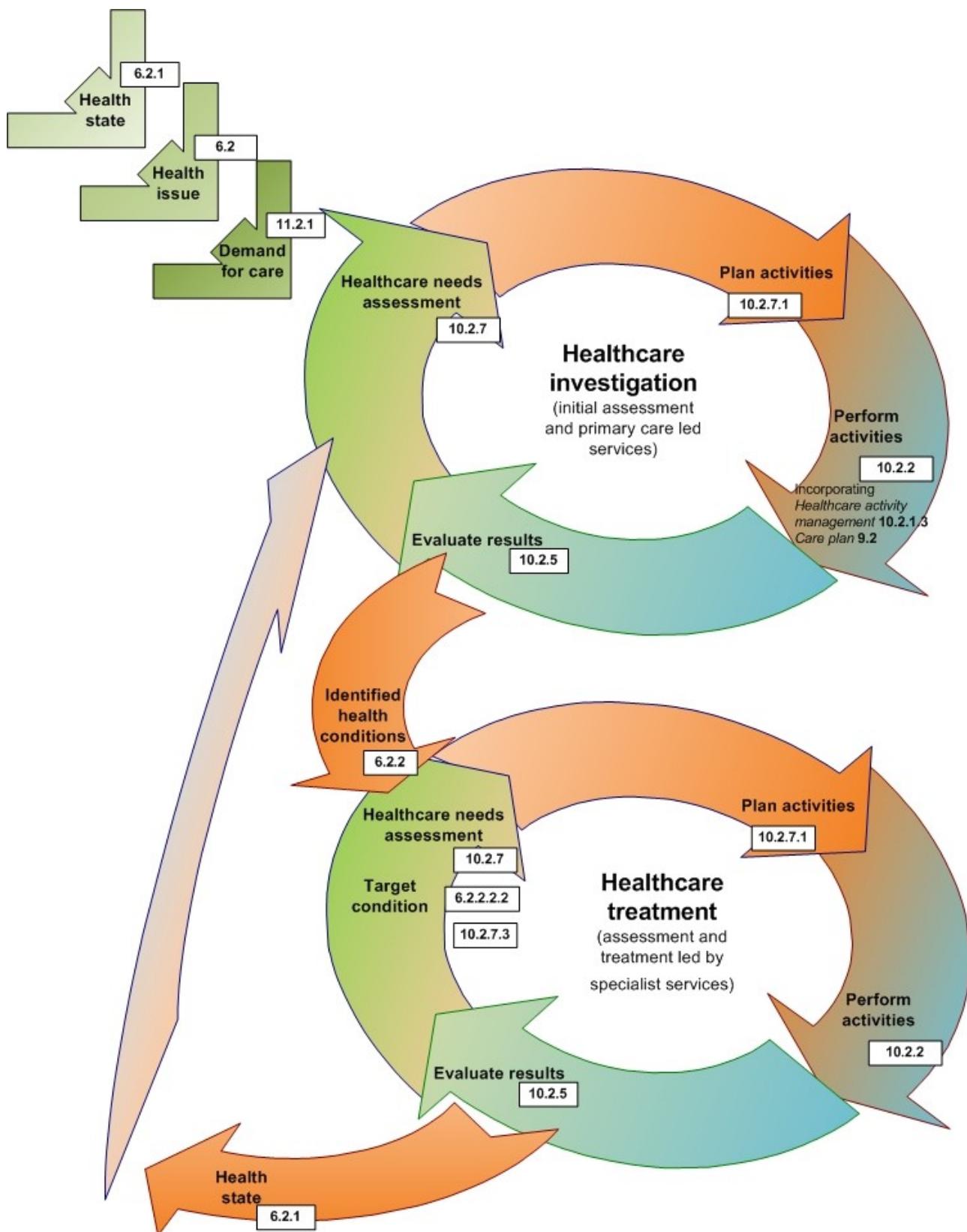


Figure 146 – Main concepts of a clinical process showing clause references (informative)

14.6.1 Basic concepts and steps in the healthcare/clinical process model

14.6.1.1. 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.

14.6.1.2. 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 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 of the process) it is important that types of inputs are clearly differentiated:

- the primary process input – the object processed, the transformation of which will produce the 'major' (primary) output as the result of a 'core' process
- the secondary resource inputs that are consumed in the process activities.

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*.

14.6.1.3. Health conditions in a healthcare process or clinical process

During a *healthcare/clinical process*, several *health conditions* (existing or potential observations of a subject's of care *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 activities* (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 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 the *healthcare / clinical process* is a *resultant condition*.

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*)

14.6.1.4. 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 activities*. The activities in the *healthcare / clinical process* have two main aims;

- to clarify the health problem (by investigations) and
- to undertake action to influence the identified problems (by treatment).

Healthcare activities are regarded as direct when they are performed in interaction with the *health state* of the *subject of care*. In this 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 activities elements* for investigation and treatment will have different statuses during the *healthcare/clinical process*; the illustrative statuses are drawn from EN ISO 12967-1: 2011.

During their performance they will have a status of 'ongoing' / '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 perceiving in the process model is to *perceive* an aspect of a *health state* as a *health condition*.

Assess: To assess is to form an opinion concerning the relevance of the *perceived 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 *investigating or therapeutic activities (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 perceptions 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*.

14.6.2 Steps in the generic healthcare/clinical process model

14.6.2.1. 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 may decide 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 *clinical process concern*. All information about *health conditions*, investigating and therapeutic activities etc. that relate to the *clinical process* can then be traced, followed and coordinated by the *clinical process 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 *clinical process concern* is decided by the *healthcare professional* that documents the information. When co-ordination 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 *clinical process concern*.

14.6.2.2. 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*, *health needs* and the *health problems*. The *healthcare needs assessment* is based on the *health needs* 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 activities* -

combined with an *informed consent* from the *subject of care* - is a kind of *healthcare mandate*.

14.6.2.3. 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 co-ordination of these continuity aspects should be documented (as a *continuity facilitator mandate*).

14.6.2.4. 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 activities 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 co-ordination and follow-up of all relevant activities in the *care plan*.

14.6.2.5. 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 *resulting 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 indications.

14.6.2.6. Assess the needs for healthcare treatment

The *health conditions* identified can be evaluated as not requiring therapeutic activities. Following consultation with the *subject of care* about this, a renewed *assessment of healthcare needs* for further *healthcare investigations* is performed. If this is also negative, the process is finished.

If the identified *resulting condition* fulfils criteria for performing *therapeutic activities elements*, an extended assessment takes place. This takes other circumstances into consideration thus providing a holistic view of the *subject of care*. This will be completed in consultation and dialogue with other *healthcare professionals* and the *subject of care* (assess needs for *healthcare treatment*).

The assessment of needs for healthcare treatment is based upon the *health conditions / health problems* – usually expressed as a diagnosis - that is concluded after the *healthcare investigations*. Other circumstances related to *health needs* of the *subject of care* will also be considered.

The assessment activity can 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*.

14.6.2.7. 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 activities in the current *care plan*.

14.6.2.8. 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.

14.6.2.9. 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 activities in the *care plan*, the clinical process outcome (its' effect on the *health state*) is observed, analysed and described as one or more *resulting conditions*.

The *resulting conditions* are compared to the *target condition* and/or to earlier observations of the same type of *health condition*. The *health needs* 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.

14.7 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.

Other 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 chapters 5 – 12 are shown below in Figure 147

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*.

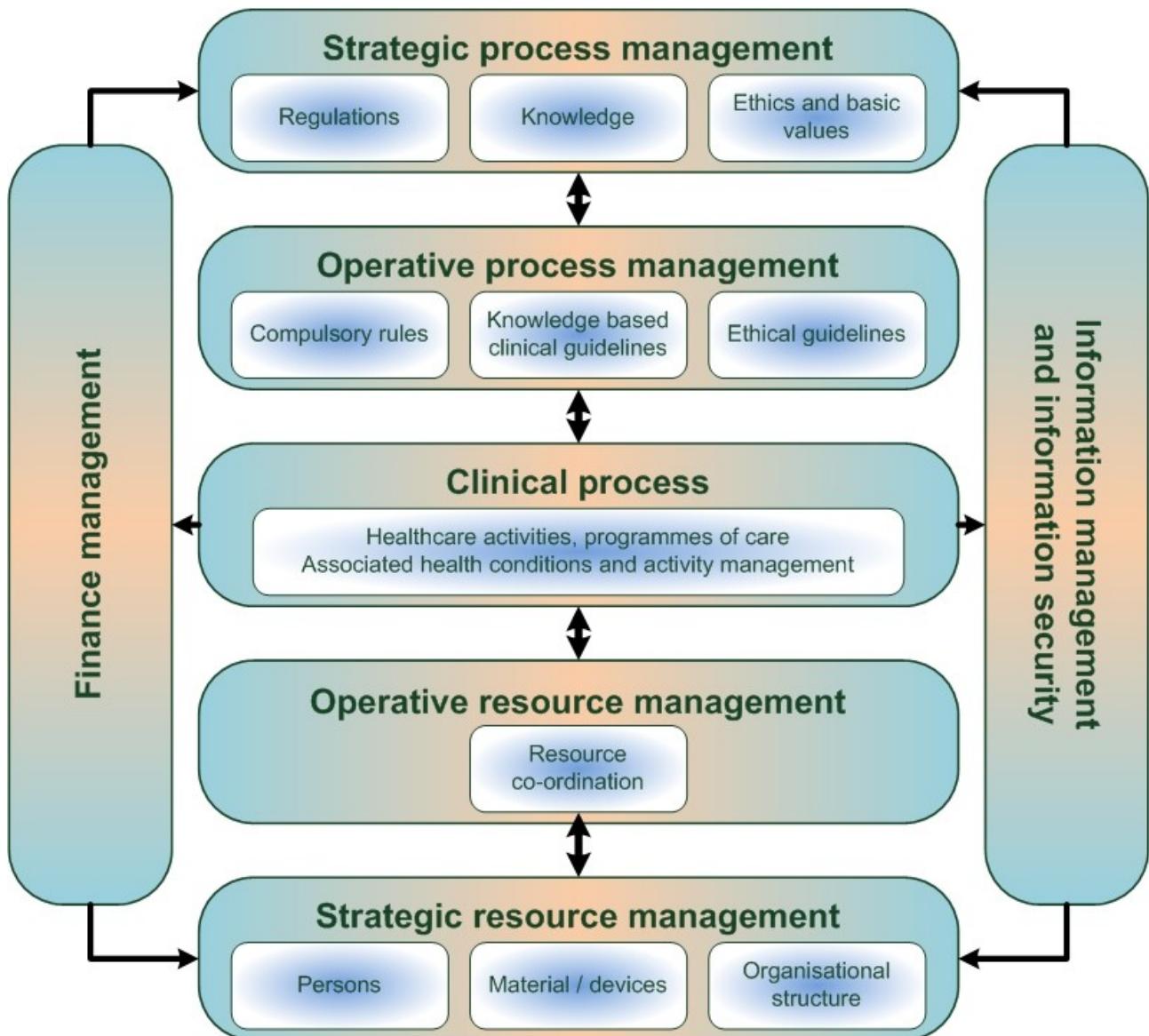


Figure 147 — Organizational information areas with references to normative clauses.

The resource area is subdivided into strategic and operational and includes personnel, material/devices and organisational 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, 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 *core care plans*, directives based on 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 documentation 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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